Introducing MMV in Access:

“Working Together to Maximise Health Impact of New Anti-Malarials”

1st MMV Access Symposium
Livingstone, Zambia
6 May 2006

Dr Chris Hentschel, CEO MMV
Why MMV Involvement in Access and Delivery Work?

- 2000  Discover, Develop, Register
- 2003  Discover, Develop, Deliver (Passive - Facilitator)
- 2005  Discover, Develop, Deliver. Active Partnership with Industry and Others
- 2006  Delivery execution phase in full swing as well as a rebalancing of the portfolio
- 07-10  Registration of first MMV products
- 10-20  Health impact begins – in time to help contribute to the MDGs
## MMV Portfolio Q1 2006 --- a development bolus:

### Exploratory Discovery Preclinical Development Regulatory

<table>
<thead>
<tr>
<th>Lead Identification</th>
<th>Lead Optimization</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSAC antagonists</td>
<td>Dihydrofolate reductase (DHFR)</td>
<td>OZ Next Generation</td>
<td>Enantioselective 8-aminoquinoline</td>
<td>OZ + PQP</td>
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<tr>
<td>Pf enoyl-ACP reductase (Fab I)</td>
<td>Pf protein farnesyl-transferase (PF-PFT)</td>
<td>New dicationic molecules</td>
<td>Isoquine (an improved aminoquinoline)</td>
<td>RBx11160 + Piperaquine</td>
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<tr>
<td>Cameroonian Medicinal Plants</td>
<td>Novel Liver Stage Antimalarials</td>
<td>4(1H)-pyridones Back ups</td>
<td>Falcipain (cysteine protease)</td>
<td>AQ-13</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>Pyronaridine - Artesunate</td>
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<td>Pediatric Coartem™</td>
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<td>Eurartokin™ (dihydroartemisinin-piperaquine)</td>
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</tbody>
</table>

### For Uncomplicated Malaria
- Efficacy against drug resistant strains
- Cure within three days
- Low propensity to generate rapid resistance
- Safe in small children (< 6 mos.)
- Safe in pregnancy
- Appropriate formulations and packaging
- Low cost of goods

- Projects in the GSK/MMV mini-portfolio
- Projects under contract negotiation
MMV will engage in these interfaces and contribute to activities beyond drug R&D where it has unique and compelling advantages as compared to these global actors.

The minimalist engagement model
The True Finish Line
High Quality affordable drug choice both for the public sector, and also to a seller near you
Counterfeits and poor quality are significant problems in private sector

Counterfeits are a significant issue, especially in artemisinin monotherapy

- Study found 38% of artemisinin bought in SE Asia shops did not contain active drug\(^{(2)}\)
  
<table>
<thead>
<tr>
<th>Country</th>
<th>% Counterfeit</th>
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<tbody>
<tr>
<td>Vietnam</td>
<td>64%</td>
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<tr>
<td>Myanmar</td>
<td>40%</td>
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<tr>
<td>Laos</td>
<td>38%</td>
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<tr>
<td>Cambodia</td>
<td>25%</td>
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<tr>
<td>Thailand</td>
<td>11%</td>
</tr>
</tbody>
</table>

- Counterfeiters getting increasingly sophisticated, e.g., holograms

Poor quality also due to lack of appropriate dosing regimen

- Togo: 70% of home treatments inappropriate\(^{(3)}\)

- Nigeria: 25% of chloroquine treatments are sub-curatives doses\(^{(4)}\)

- Zambia: 62% of people don’t know dosing of malaria treatment for adults, and 75% for children\(^{(5)}\)

- Kenya: 96% of children treated with privately purchased chloroquine received inadequate doses, and 98% received it for less than 3 days\(^{(6)}\)

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(1) WHO factsheet on counterfeit medicines, May 2005  
(2) “Fake artemisinin in southeast Asia”, The Lancet, June 16, 2001  
(3) Deming et al, 1989  
(4) Ejezie et al 1990  
(5) Makubalo 1991  
(6) Kirigia et al 1998  
Source: Secondary & primary research
ACT a Positive Story but:

- Artesunate + amodiaquine
- Artemether/lumefantrine
- Artesunate + SP
- In process of Policy Change
- No Information Available

Source: WHO Facts on ACTs, Nov 2005, WHO Website

BUT in all countries ACT are a minor component of actually used drugs and Artemesinin Monotherapy is common/dominant:

- More than 200 drugs available on market
- Only 50 % of 1st and 2nd Line treatment (SP and AQ in 2002) were officially registered

Source: A Amin & R Snow, Malaria Journal 2005, 4; 36
ACT a Positive Story but many issues remain:

- Weak public sector distribution systems
- Private sector: can ACTs displace low quality drugs?
- Quality Assurance and training in private sector
- 1st trimester?
- Lack of choice & availability of high quality drugs
- Insufficient funds to implement and to sustain drug supply
- Mono-therapy Issue; Counterfeits; Poor Quality Drugs
- Demand Forecasting: a challenge
- Pricing of new drugs
- Information Requirements: lack of good data for decision-making

ACT USE IS INCREASING, BUT REQUIRES FURTHER SUPPORT
NEW MMV DRUGS OFFER OPPORTUNITIES: INCREASED CHOICE
Q: Who Spends on Malaria?
A: Both Public AND Private Sectors (Individual Households)

Kenya: ~60% of fevers treated at home with locally purchased herbs or drugs

Ghana: ~66% use Licensed Chemical Sellers (LCS) for first line therapy

Togo: ~83% of fevers treated at home

Burkina Faso: ~87% of mild and 54% of severe fevers treated outside professional services

Source: “Planning for Success”: BCG research for MMV, 2005
DOES THE PUBLIC SECTOR REACH THE POOR?

Ndola Prata, MD, MSc
Bixby Program & CEIHD
School of Public Health
University of California, Berkeley

Dar es Salaam
United Republic of Tanzania
December 10–12, 2003
Authors Conclusion:

• In most countries the choice of the poor is usually between using private services or not using services at all.

• The use of private health care does not differ significantly by socio-economic group.

• Financial burden on households is greater for the poor.
MAXIMISE HEALTH IMPACT THROUGH LAUNCH OF NEW DRUGS AND FORMULATIONS

Harness both private AND public supply strengths
Public – Private Sector Dynamics

**Public Sector**
- ACT – “generic” demand creation
- Distribution to public sector consumers
- Ensure access for vulnerable groups
- Local demand creation
  - Distribute to wider populations
  - In some cases: additional “niche” supply

**Premium Private Sector**
- Brand-specific demand creation
- Distribution to private sector consumers

**Non-Premium Private Sector and NGOs**
- RAPID demand creation
- Expansion of market from urban to rural setting

**Maximum Public Health Impact**
- Patient awareness and demand
- Ensure access for vulnerable groups
- Local demand creation
Key Questions for Roll-out of New Drug:
AIM: MAXIMISE HEALTH IMPACT

- Where & When to Launch: ensuring maximum availability
- Demand Forecasting and Manufacturing Capacity
- Price & Financing: lowest possible price, maximise availability
- Distribution Channels (from manufacturer to warehouse)
- Delivery Channels (public / private pharmacy, social marketing, EPI link up etc)
- Quality Assurance, Pharmacovigilence
- Resources Required: partners, resources, information
- Measuring Health Impact
Strategy: Public-Private Partnership is key for Delivery of Antimalarial Drugs

**MMV Input**
- $$
- IPR
- ‘Need’ Profile
- Partner Drugs
- Link to Policy/WHO, etc
- Link to downstream partners
- India Office
- Link ‘pull’ mechanisms – GFATM, PMI etc
- Link to IFC

**Pharma + Multinationals**
- Manufacturing
- QA
- Regulatory
- Delivery Assets
- Delivery Know How
- Liability Insurance

**Public**
- Drug choice
- Affordable supply in markets relevant to Health Impact

**Private**
- Lower risk and cost
- Premium private market
- PR & HR Benefit

**Joint Delivery**
... but the direction is clear

<table>
<thead>
<tr>
<th>Chapter 1</th>
<th>Chapter 2</th>
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<tbody>
<tr>
<td><strong>Discover/Develop</strong></td>
<td><strong>Deliver</strong></td>
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<tr>
<td>• CSO</td>
<td>• VP Global Access</td>
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<tr>
<td>• Partners</td>
<td>• Partners</td>
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<td>• Advisory Group</td>
<td>• Advisory Group</td>
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<tr>
<td>• Project Plan</td>
<td>• Global Access Plan</td>
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<tr>
<td>• Project Staff</td>
<td>• Project Staff</td>
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<td>• Budget</td>
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Delivery Access Plan Imperatives for MMV and Partners

- Availability
- Affordability
- Acceptability & Quality
- Delivery
Proposed MMV access plan - Availability

**Policy Environment**
- Approval by SRA / National Regulatory Authority?
- Is drug on WHO/national EDL?

**Product Development**
- What is the target population?
- Is formulation appropriate for storage and distribution?

**Demand**
- What is the local market like?
- Which countries will be covered?
- What other treatment options are available?

**Manufacturing**
- Selection criteria?
- Is raw material secured?

**Regulatory**
- Is it approved by NDRA?
- Will/When/where will Phase IV be done?
Proposed MMV access plan - Affordability

Affordability

Pricing

- How does price impact on existing products?
- What is the final price to consumer

Financing

- How do mark-ups and distribution choice affect consumer price?
- Is ex-factory price limit / corridor in the contract?
- What financing sources are available?
- Will GFATM fund the product?
- What are other affordability issues?
Proposed MMV Access Plan - Acceptability & Quality

Acceptability

- What training and/or incentives are needed for providers?
- Are consumer education programs developed?

Product QA

- Are standards established?
- How can MMV ensure standards are met?

Pharmacovigilance

- Is there a monitoring program in place?
Proposed MMV Access Plan - Delivery

- Is supply chain established?
- Have demand forecasts been done?
- What are the coverage needs?
- Have distribution partners/systems been identified and developed?
  - Public sector
  - Private sector

How to evaluate coverage levels?
## Global Access Plan – Example Milestone/Activity calendar

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tbody>
<tr>
<td>Q1</td>
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<tr>
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### Year 1
- **Company GLT Established**
- **Trials / Product Development continue**
- **Demand Assessment**
- **Interaction with regulatory agencies**
- **Review Contract**
- **Section Priority Countries & Understanding Markets**

### Year 2
- **Dossier Submitted**
- **Phase IV Trials**
- **Pricing Discussion**
- **Procurement & Supply Chains Identified**

### Year 3
- **Launch in Private Sector**
- **Assess Impact**
- **Pharmaco-vigilence Aspects Reviewed**
- **Demand Assessment**
- **Initiate financing discussions with funding agencies**
- **Prepare Policy Envirmt – WHO PreQual / Recommend / EDL / STGs**
- **Preparation of national policy environment**
MMV: ...Now Creating a Future Network for Access & Delivery


- Pharmaceutical partner
- Donor
- Research/Technical Institute
- National Malaria Control Programme
- International agency
- Implementation or Collaboration Partner

Inst. OneWorld Health
Gates Foundation
World Bank
CGD
ExxonMobil
USAID
MSH
RBM Partnership
LSHTM
Irish Aid
GlaxoSmithKline
Netherlands Aid
Swiss Aid
WEF
WHO
Sigma-Tau Industrie Farmaceutiche Riunite
Ranbaxy Laboratories Limited
Holley Pharm
Korea Shin Poong Pharm. Inc.
Pharmerit
World Bank
CGD
ExxonMobil
USAID
MSH
RBM Partnership
LSHTM
Irish Aid
GlaxoSmithKline
Netherlands Aid
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ExxonMobil
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RBM Partnership
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Irish Aid
GlaxoSmithKline
Netherlands Aid
Swiss Aid
WEF
WHO
Sigma-Tau Industrie Farmaceutiche Riunite
Ranbaxy Laboratories Limited
Holley Pharm
Korea Shin Poong Pharm. Inc.
Many Different Areas of Expertise

Swiss Tropical Institute

WHO

GFATM

GSMF Ghana

Institute One World Health

Holley Pharm

NMCP Zambia

DFID

PSI

DNDi

TDR

Malaria Consortium

NMCP Malawi

BHP Billiton

MSH

RBM Partnership

FIND

Gates Foundation

Wellcome Trust

Sigma Tau

World Bank

LSHTM

CGD

CFW Shops Kenya

Pharmaceutical Society Ghana

NMCP Zambia

USAID

Novartis

USAID

Novartis

USAID

Pharmaceutical Society Ghana

NMCP Zambia

USAID

Novartis

USAID

Pharmaceutical Society Ghana
Discussion – How can we work together?

• Where & When to Launch: ensuring maximum availability
• Price & financing: lowest possible price, maximise availability
• Distribution Channels (from manufacturer to warehouse)
• Delivery Channels (public / private pharmacy, social marketing, EPI link up etc)
• Demand Forecasting and Manufacturing Capacity
• Quality Assurance, Pharmacovigilence
• Resources Required: partners, resources, information
• Measuring Health Impact
THANK YOU

Curing Malaria Together www.mmv.org

Medicines for Malaria Venture