MMV’s Access & Product Management Strategy

Siem Reap, Cambodia – 24-26 February 2015

George Jagoe, EVP, Access & Product Mgmt
to reduce the burden of malaria in disease-endemic countries by the discovery, development, and delivery of new, effective and affordable antimalarial drugs.

**OUR MISSION**

Drugs only become medicines once administered to patients.
But the journey from molecule to medicine to patient impact is not seamless. There are many gaps in the road to patient impact.
Access and Product Management fills the gaps throughout the entire product lifecycle.
Access works closely with its pharma partners and country stakeholders to minimize time-to-market for new products and to ensure acceptability of products for maximum patient impact after launch.

Injectable Artesunate, a newly WHO-recommended treatment for severe malaria was moving slowly in terms of introduction, acceptance, and widespread use in African countries two years after WHO prequalification and guideline change. Slow uptake was costing lives. MSF estimated that approximately 200,000 additional lives could be saved each year if countries switched from quinine to Injectable Artesunate.

**CASE STUDY**

**INJECTABLE ARTEESUNATE**

**MMV** and its partners CHAI and Malaria Consortium secured a $34 million, 3-year grant from UNITAID that is:

1. **Supporting the direct procurement and scale-up of Inj AS in six high-burden African countries** (with 4.7 million vials distributed in the first year)

2. **Negotiating the entrance of a second manufacturer of Inj AS**

3. **Introducing first-time WHO-prequalified artesunate suppositories for the pre-referral treatment of severe malaria**

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Global use in 2014 of Injectable Artesunate (WHO-prequalified)

11.5M vials ordered from Guilin Pharma

Prequalified Inj AS has been registered in and delivered to 20 African countries and 5 Asian countries.

With 25 million artesunate vials ordered since WHO prequalification,

This translates to a potential 160-170K children’s lives saved (vs. if treated with quinine.)
Severe Malaria: Recapping the Partners and their roles…

- PRODUCT DEVELOPMENT
- REGULATORY APPROVAL
- PRODUCT READINESS
- POLICY & FINANCING
- DISTRIBUTION & DELIVERY
- PATIENT UPTAKE

Logos: Guilin Pharma, World Health Organization
Severe Malaria: Recapping the Partners and their roles...
Treatments for Uncomplicated Malaria
Eurartesim was first introduced in Cambodia in 2012, as part of the country’s participation in the Global Fund-based Affordable Medicines Facility for Malaria.

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| Product category | • Artemisinin Combination Therapy (ACT)  
|                  | • Dihydroartemisin + piperaquine |
| Therapeutic indication | • Treatment of uncomplicated *P. falciparum* malaria in adults, children and infants >5kg |
| Dosing | • Once daily for 3 days |
| Efficacy | • 28 day PCR-corrected ACPR 94.7% - 99.9%  
|          | • 42 day PCR-corrected ACPR 91.5% - 99.3% |
| Key features | • Once daily  
|             | • Good post-treatment protection |
| Challenges | • Communicating new evidence about demonstrated safety (e.g. Cochrane 2014) |
| Status | • First stringent approval EMA 2011. WHO prequalified in 2015  
|         | • Approvals in Asia (Cambodia, India), and Africa (Burkina Faso, Ghana, Mozambique, Nigeria, Tanzania, Zambia*)  
|         | • Submitted for WHO prequalification in 2012  
|         | • Ongoing regulatory review in 2 African and 7 Asian countries |
| Next milestone | • Evaluation of use in pregnancy (IPTp alternative) and MDA in dual infection settings  
|             | • Evaluation as MDA tool in Southern Africa |
Pyramax has been evaluated in Cambodia as part of its Phase 2 and Phase 3 program (between 2005 and 2008).

It is currently the focus of an efficacy study in Western Cambodia, an area of artemisinin-resistant malaria.
# Coartem Dispersible

**Novartis**

| **Product category** | • Artemisinin Combination Therapy (ACT)  
• Artemether + lumefantrine |
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<td><strong>Therapeutic indication</strong></td>
<td>• Treatment of adults and children &gt;5kg with uncomplicated <em>P. falciparum</em> infection (including mixed infection)</td>
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<tr>
<td><strong>Dosing</strong></td>
<td>• Twice daily for 3 days</td>
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The most widely distributed WHO-prequalified malaria medicine designed specifically to meet the needs of children.

Over 250 million courses of medicine distributed since 2009.
As a fixed-dose combination, ASMQ meets a critical role as an important ACT for use in the emergency response to drug resistance in the Greater Mekong region.

* Incorporated into MMV portfolio in 2015 (post-launch) through collaborative transfer from DNDi.
**ASAQ***

Sanofi / DNDi

| Product category | • Artemisinin Combination Therapy (ACT)  
|                  | • Artesunate + Amodiaquine (FDC)       |
| Therapeutic indication | • Treatment of adults and children >5kg with uncomplicated *P. falciparum* |
| Dosing           | • Once daily for 3 days                |
| Status           | • Widely used in Central and West Africa.  
|                 | • 2016 publication of results from Phase IV active pharmacovigilance study in Ivory Coast. |

The second most widely used WHO-prequalified ACT, with major uptake primarily in Central and West Africa.

* Incorporated into MMV portfolio as part of Phase IV post-launch safety study in West Africa in collaboration with Sanofi
P. Vivax Malaria

(1) Preparing for the introduction of single-dose radical cure

(2) Tapping a living «laboratory» to understand community delivery of radical cure
Tafenoquine: Key considerations for launch planning
Opportunity for Tafenoquine (+ G6PD test)

• Tafenoquine responds to a real unmet medical need

• Favourable policy environment:
  • WHO new guidance on *P. vivax*
    • Radical cure recommended in **all** transmission settings
    • G6PD testing before radical cure – with existing tests or referral to higher levels
    • WHO ERG recommendation on specific G6PD test

• Push for elimination
Country prioritization criteria

- Epidemiology
- Regulatory
- Funding
- G6PD ease
- Network
Prerequisites to accelerate tafenoquine impact in countries

1. Registration in key countries

2. Inclusion in treatment guidelines – WHO and National

3. Appropriate and affordable package: G6PD test + TQ

4. Appropriate supply chain

5. Modified clinical practice
Update on Comprehensive Case Management Programme (CCMP), Odisha
CCMP is an operational research study under programmatic conditions

**Purpose**
- Assess the impact of universal access to diagnosis and treatment on malaria incidence in different transmission settings
- Better define the malaria burden and epidemiological profile in mixed infection environments
- Understand and address the challenges with radical cure

**Partners**
- Principal investigators: NIMR, NVBDCP / Odisha
- Support: MMV, WHO

**Study area**
- Odisha, India
- 8 blocks (control and intervention) in 4 districts with different transmission intensity
- Population of 900K

**Timelines**
- 2013 –2016
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