Essential elements of the access strategy:

Lessons learned

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Medicines for Malaria Venture

Lessons Learned in Developing MMV Access Strategy

- **Consistency with Discovery and Development agenda**
- **Iterative Development with input from wide range of key stakeholders and partners**
- **Simplicity of Conceptual Framework**
- **Readily linked to annual access plans for each MMV product**
- **Firm but not rigid – adaptable over time**

MMV-Partners Drug Development Pipeline

Research

Lead Gen

- Novartis miniportfolio
- GSK miniportfolio
- Broad/Genzyme miniportfolio
- Pfizer Whole cell screen
- sanofi aventis Orthologue screen
- Natural Products 5 Projects
- Kinases Monash
- Whole Cell screen AstraZeneca
- Other Projects 13 Projects

Lead Opt

- KAI407 series Novartis
- Pyridone GSK
- DHODH UTSW/UW/Monash
- Aminoindole Broad/Genzyme
- Ozonide backup Monash/UNMC/STI
- Quinoline Methanols WRAIR
- DHODH Broad/Genzyme
- KAC776 series Novartis
- KA558 series Novartis
- Aminopyridine UCT/STI/Monash
- Quinolones USF/VAMC/Monash
- SSJ-183 * Synstar

Translational

Preclinical

- MK 4815 (Merck)
- KAE 609 Novartis
- P218 DHFR (BIOTEC/Monash/LSHTM)

Phase I

- GSK 932121 GSK
- Tafenoquine GSK
- OZ 439 (Monash/UNMC/STI)

Phase IIa

- Iv artesunate Guilin
- Artemisone UHKST

Development

Phase IIb/III

- Arterolane/PQP Ranbaxy
- AZCQ Pfizer

Registration

- Eurartesim™ sigma-tau
- Pyramax® Shin Poong/University of Iowa

Phase IV

- Coartem®-*D* Novartis APPROVED
- ASAQ Winthrop sanofi aventis/DNDi APPROVED

Medicines for Malaria Venture

MMV Access & Delivery: Vision and Mission

MMV A&D's Vision

We will contribute to the access and delivery agenda to control, eliminate and ultimately eradicate malaria by supporting access to and availability of efficacious, safe, affordable and quality-proven medicines that will treat and when appropriate prevent this infection, wherever it occurs.

MMV A&D's Mission

To ensure that medicines which MMV has helped develop are accepted, made available and correctly used in key countries where effective partnerships will enable us to deliver a real health impact and document and quantify the results of our work.

Access Strategy - Iterative Development

With input from

- **“activated” Board members**
- **Pharma Partners**
- **Implementing Partners**
- **WHO Global Malaria Programme and AFRO**
- **RBM Partnership**

- **And conceptual guidance from BCG during development of 2008-2012 business plan**

MMV Global Access & Delivery -
Three Strategic Pillars Supporting Health Impact

Health Impact

Acceptance

- Globally (normative)
- Locally (4Ps - policy, practices, preferences, politics)

Expansion

- Improved public delivery
- More affordable private delivery
- Innovative community delivery

Measure / Evaluate / Feedback

- Real-life effectiveness
- Head-to-head in multiple settings
- Evidence-to-policy

MMV Access & Delivery: Acceptance

The role of the MMV A&D Team, together with the MMV R&D team, is to facilitate the product acceptance work of our pharma partners[1], primarily by leveraging our good working relationships and close proximity to the normative and financing entities whose support is critical for gaining such acceptance by endemic countries.

Once these endorsements are obtained, the MMV A&D Team will work with a wider range of partners to leverage uptake of the new products and ensure collection of adequate safety, efficacy and effectiveness data in defined countries.

Understanding how a drug is used in real life settings is critical to facilitating its acceptance. MMV A&D will work with all relevant partners[2] to develop understanding of this and how its products might be developed further to encourage broader acceptance[3].

[1] MMV's pharma partners will normally take the lead in product manufacturing and preparing product documentation and third party references. They will also be primarily responsible for collecting post-Marketing Surveillance (PMS) data, obtaining inclusion in essential medicine lists and treatment guidelines, and seeking Global Fund QA-approval.

[2] Including through collaboration with the Phase IV and ACT Consortia.

[3] Including field testing of training materials and packaging of our pharma partners' products to achieve optimal compliance and ease of use.

MMV Access & Delivery: Expansion

Once an MMV-backed drug has been registered and launched, we will work with our partners to expand product reach in a defined number of key countries through:

- Initiatives that improve product availability and correct case management in the public sector (including innovative community health worker programs);
- Affordability-focused innovations that enable poor patients to obtain and appropriately use quality treatment through the private sector while providing incentives for the private sector to displace older ineffective drugs with new quality treatments.

NB We will in parallel encourage the MMV R&D Team and pharma partners to conduct Phase IIIb studies to extend product use to appropriate patient groups or malaria indications not covered by the initial approvals. We will support the efforts of policy makers and practitioners who seek to change product status from Prescription Only Medicine (POM) to Over The Counter (OTC) where widespread use of the product has demonstrated its excellent safety profile in real world settings. We will also support the efforts of drug regulators who seek to expand the types of outlets authorized to dispense ACTs to patients.

MMV Access & Delivery: Measure / Evaluate / Feedback

- As a follow on to our acceptance and expansion initiatives, we will work with MMV Medical and our partners to develop models that will track, measure, evaluate and document the health impact of our pharma partners' products, including the impact of innovative delivery mechanisms that we support.

- We will take upon ourselves to communicate broadly the results of our initiatives.

- Once the newly emerging generation of quality and effective antimalarial products is accepted widely, we will also participate in broadening the knowledge base as to how these drugs – including those developed outside of the MMV pipeline -- are used and perform in real life settings in order to inform the future global research agenda.

Example – Linking A&D strategic pillars to 2010 Coartem Dispersible post-launch

Health Impact

Acceptance	Expansion	Measure / Evaluate / Feedback
1. Collaboration with WHO-EMP and Dalberg – national policy review initiative for child-friendly meds. 2. Collaboration with Sante Afrique and UNICEF. Strengthen IMCI policy and program management to use pediatric-designed medicines for malaria	3. In Mali and Malawi, with PSI, distribute 1.8m doses via ICCM program. 4. With KEMRI, routine monitoring of ACT availability and proper case management in three countries in 2010	5. Evaluate effectiveness of Coartem D when used by CHWs

Access Strategy – Firm but Adaptable

Examples of changing landscape – and pressure to re-visit A&D strategy

- **Local Manufacturing – evolving priority?**
- **Accelerating generics to expand affordable access – a strategic crossroads?**