Taking on the issues one by one, the work of the A&D team is focused on three areas of activity (see graphic above):

- Ensuring both the adoption of new antimalarial medicines recommended by the WHO and their correct use
- Expanding their reach by making them affordable and available
- Measuring the impact of new drugs post-launch

MMV’s partnerships have resulted in the successful launch of Coartem® Dispersible (artemether/lumefantrine) with Novartis in 2009 and the WHO prequalification of Guilin’s artesunate injection in late 2010. We expect two additional product launches in 2011/2012 (dihydroartemisinin-piperaquine and pyronaridine/artesunate). To ensure these new medicines reach those who need them most and ultimately help reduce the global burden of malaria, the A&D team is working with pharmaceutical partners, national health officials, country-level partners, and policy makers in these three areas of activity.

Increasing access to lifesaving antimalarials remains a multi-dimensional challenge that MMV’s A&D team continually seeks to overcome with innovative approaches and strong implementing partners.

Almost half of the world’s population is at risk from malaria and every year around 700,000 children lose their lives to this devastating disease. Among the many reasons for this unacceptable statistic is the fact that patients and caregivers have sorely limited access to effective antimalarial medicines.

The challenges facing access to medicines start at the community level, where rural people often have to walk hours to a government health centre that may well be inadequately stocked with basic medicines. Or, they might have to turn to private drug sellers, where quality medicines are in short supply and exorbitantly priced. The issues continue right up to the policy level – where adoption of the latest life-saving treatment is often complex and time consuming.

MMV’s Access and Delivery (A&D) team was established in 2006 to help tackle these issues, ensuring that new innovative antimalarials have a smooth journey to those in need, saving lives without delay.

### Ensuring acceptance
- Supporting the WHO’s ‘Better Medicines for Children’ programme
- Positioning new products for country registration
- Supporting policy reviews and revisions in response to new and improved medicines
- Developing and testing packaging to ensure correct dispensing and use

### Expanding reach
- Expanding community access to treatment by supporting integrated rural health delivery models
- Private sector subsidy schemes to expand access to effective treatment
- Supply chain management innovation and improved system performance
- Advocacy and mobilization to highlight gaps in ACT & RDT scale-up

### Measuring impact
- Market impact and evaluation
- Promoting effectiveness studies (Phase IV) for quality ACTs

### Access in action
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### Defeating Malaria Together

### Access in action
Putting children first

Across the world, drug companies develop medicines to adult specifications. Only after those drugs have been used widely and accepted as safe do they consider developing child-friendly versions. But in the case of malaria, children are the main victims. Between 85% and 90% of all deaths from malaria occur in children under 5 – that's around 700,000 deaths each year.

Given this massive toll, MMV works closely with its pharma partners to develop child-friendly formulations of their medicines that simplify dosing and enhance paediatric tolerability.

The impact of Coartem Dispersible

Nurses, doctors and caregivers often struggle to get sick children to take their medicine. Antimalarial medicines, however, present their own additional challenge – the bitter taste of artemisinin derivatives can cause a gagging or vomiting reflex in children.

Even more challenging, after the first dose is given by a healthcare professional, parents or caregivers must continue to treat their sick children at home. This makes it harder to guarantee they will complete their treatment course, which is critical to ensure a complete cure. Incomplete dosing can also contribute to a larger problem – the development of drug resistance.

Designing high-quality formulations that encourage compliance and acceptability has long been considered an important feature of child-friendly medicines in developed countries. After several years in clinical development Coartem Dispersible broke through the wall of neglect that denied sick children in the developing world access to malaria treatment tailored to their needs.

“[Coartem Dispersible]… is a great advancement in paediatric malaria treatment. It is easy to administer, with a sweet taste that children love, and this means better compliance and ultimately less deaths from the disease.”

Dr Bernhards Ogutu, Paediatrician, Kenya

Rosemary’s story: “It’s like he was completely healed”

“My name is Rosemary Omolo. I come from a small town between Ombeyi and Kasongo in Kenya and work with orphans and widows. Most of the orphans live with their grandparents. Malaria is a burden on all of us parents.

When a child gets malaria most parents give them painkillers for a whole month. Sometimes 2 week’s continuously on the painkillers. By the time we come to know of this, the child’s blood has lots of malaria.

My son’s name is Hope John Kennedy Otieno. He started feeling unwell on Friday evening and I gave him panadol. On Saturday morning he woke up well, he was cheerful and played a lot until in the afternoon when he started complaining and I gave him more panadol. The same followed on Sunday – he woke up well but in the evening it was raining and when I woke him to eat, he had fever and vomited the whole night. It was on Monday that I decided to bring him to the hospital for treatment. He was treated with Coartem Dispersible and it’s like he was completely healed. We are waiting to go home now.

What makes me afraid when we go to hospital; we are told that children under 5 years die because of malaria very fast. When I hear that a child has malaria I desire that they get quick treatment especially when the child is below 5 years. The day we came I had fear in my heart. Today I am happy he is OK and we are going home.”

In the 25 months following MMV and Novartis’ co-launch of Coartem Dispersible in February 2009, more than 64 million treatments have been distributed to 35 countries, mainly in Africa. MMV is proud to have contributed to this important breakthrough.

Text and images courtesy of Novartis
Fostering uptake of better medicines for children

MMV helped bolster the impact of Coartem Dispersible in 2010 by helping inform, train and raise awareness amongst endemic-country policy makers of the need to consider child-friendly medicines as a critical element of their national malaria protocols. We studied policy adoption frameworks for paediatric medicines, and presented the findings at the 2010 American Society of Tropical Medicine and Hygiene conference and the ‘Better Medicines for Children’ partners meeting at WHO. In addition, we worked with partners to introduce the medicine via innovative new pilots to expand rural access to treatment through community-based health workers (see orange box).

In line with WHO’s recommendation to confirm diagnosis before treatment, MMV has also supported the analysis and reporting on progress in scale-up of rapid diagnostic tests (RDTs) and artemisinin combination therapies (ACTs) at country level. A first report on national ACT/RDT availability, financing and gaps was produced in 2010, and the second report is being prepared in collaboration with the African Leaders Malaria Alliance (ALMA).

Delivering the best care for severe malaria

In late 2010, the long awaited results of the AQUAMAT trial in Africa provided conclusive evidence that children with severe malaria had a 22% better chance of survival if treated with artesunate injection compared to quinine.1 As a result, WHO has modified its Standard Treatment Guidelines to recommend the use of artesunate over quinine for severe malaria in children and adults.

MMV’s R&D team worked closely with a Chinese manufacturer of artesunate injection, Guilin Pharmaceutical, to help them become the first manufacturer to obtain WHO pre-qualification for this life-saving medicine.

With this stamp of approval and conclusive evidence in hand, MMV’s A&D team is working closely with country-level partners and national governments to support the policy change, training and financing requirements needed to enable artesunate injection to rapidly reach patients who need it.

Expanding reach

Helping close the ‘Affordability Gap’

In September 2008, MMV and the Ministry of Health, Uganda launched the CAPSS1 pilot to assess the feasibility and impact of providing a subsidized ACT through the private sector as a means of improving access to treatment. The pilot was designed along the lines of the global subsidy scheme, AMFm2, comprising a subsidy and supporting interventions including training and demand-generation campaigns.

CAPSS has validated the hypothesis that ensuring ACTs are affordable will drive availability and uptake, thereby displacing ineffective treatments. By May 2010, the subsidized drug, branded ‘ACT with a leaf’ accounted for 69% of all antimalarials purchased from licensed drug shops for children under 5 years compared to less than 1% at the outset. Access to effective treatment within 48 hours of fever onset for children under 5 has increased significantly from 4% to 27%.

The results from CAPSS helped inform and garner support for Phase 1 of the AMFm. CAPSS also provided the rationale and evidence for the use of a universal logo for AMFm products – the logo used by the pilot was adapted and is now the official AMFm product logo. MMV also drew on the experience with CAPSS to help develop a branding and communications toolkit to support AMFm implementation.

1 CAPSS: Consortium for ACT Private Sector Subsidy; Ministry of Health, Uganda; MMV; National Drug Authority; Programme for Accessible Health Communication (PACE, formerly PSI); Surgipharm and the Malaria Consortium
2 AMFm: Affordable Medicines Facility, malaria, hosted by the Global Fund to Fight HIV/AIDS, TB and Malaria

Measuring impact

Understanding antimalarial market dynamics

Unlike in high-income countries, medicine purchasing patterns and volumes are not readily known in most malaria-endemic countries. Without a better analysis of how all antimalarials drugs are purchased and distributed in these countries, it remains difficult to measure the large-scale impact of new ACTs supported by MMV. A better understanding of the market supports national pharmaceutical planning, allows comparison of supplies relative to requirements, and supports pharmacovigilance and local investment decisions.

MMV has worked closely with the Government of Zambia and IMS Health3 to gain access to the country’s antimalarial importation history over a multi-year period, and to begin to construct a rolling view of which antimalarials are flowing into the country. The data from this project will permit the government to gather new insights and monitor trends in the market share of different classes of pharmaceutical products over time.

Given the importance of ACTs to public health, MMV and IMS are currently exploring the concept with other interested countries, to assist them in gathering, analyzing and understanding the flow of malaria drugs in-country, and gather insights into the availability and uptake of ACTs and other antimalarials nationally.

3 IMS Health is an international company that collects pharmaceutical market and sales data and provides consulting services to the pharmaceutical industry.

“This work is a strong example of MMV’s willingness to address fundamental issues which are often neglected.”

Mrs Eunat Mwape, Director General, Pharmaceutical Regulatory Authority, Zambia