

# MMV at a Glance

## MMV: Past, Present, and Future

In 2000, MMV was a newcomer to the world of anti-malarial drug research. More people were dying from malaria than ever before. The malaria parasite had become resistant to widely-used drugs, including two inexpensive medications, chloroquine and sulfadoxine/pyrimethamine. New drugs were desperately needed as malaria continued to afflict countless millions and the death toll in Africa showed an alarming increase. In addition, due to cost, poor health systems, inadequate distribution networks, and policy challenges, existing drugs were often not reaching the poor.

The pipeline for new antimalarials was virtually empty. This was to be expected, as a Global Forum for Health Research study had revealed that only 10% of the world's new drug innovation was targeted at diseases threatening 90% of the world's population. Motivated by this glaring



*“MMV is a ‘3D’ organization with a mission to Discover, Develop, and Deliver effective and affordable antimalarials.”*

*Win Gutteridge, Chair, MMV's Expert Scientific Advisory Committee*

inequity, and the need to act in the face of a projected public health disaster due to escalating drug resistance, MMV started out modestly with only USD 4 million in its purse and three early-stage projects in its portfolio. However, it was not short on ambition. It aspired to discover and develop at least one new safe, effective, and affordable anti-malarial drug before the end of the decade. Today, with four new artemisinin-based combination therapies (ACTs) in the last

stages of development, MMV is set to exceed that target.

The anticipated launch of four new ACTs by 2009 presented a new challenge for MMV. How would we ensure that these life-saving drugs reach the children and the rural poor, who badly needed them? In response to this question we have added a *deliver* component onto our well-established *discover* and *develop* core functions. We will work to ensure that the drugs

expected to soon emerge from our pipeline will swiftly reach patients and have the required health impact.

### Partnership model

Over the years, MMV has nurtured and developed innovative partnerships with scientists and researchers from both public and private sectors. The strength of this public-private partnership model and the rigorous management of our portfolio *p2* ▶

**MMV's four new fixed-dose artemisinin combination therapies (ACTs) are expected to obtain international registration by the end of 2008.**



**Medicines for Malaria Venture**

make us a highly cost-effective and productive research and development (R&D) organization. Today, we work with over 80 partners and more than 600 scientists and clinicians in 34 countries. Each pharmaceutical, academic, and endemic-country partner brings expertise, enabling technologies, and research facilities. Generous funding from private foundations and governments is used to leverage further private sector assets. The success of this operational model creates a virtuous circle that has brought us new supporters and stakeholders.

MMV's portfolio of drug discovery and development projects has grown to over 30 projects. It now comprises the largest and most diverse portfolio of antimalarial drug projects in history, including 19 completely new classes of drugs in discovery. At the development end of the pipeline, the first of several new drugs registered by a stringent regulatory authority is expected to gain market authorization between 2008 and 2010.

Rigorous selection processes are coupled with support for the most promising candidates and quick termination of those that miss milestones or do not reach MMV's demanding product profiles. This industry-style portfolio management is not easy to execute but is essential if our growing R&D expenditure is to be aligned effectively to our highly-focused mission.

All our development work is executed according to ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines.

### Future needs

It is universally accepted that both innovation and the increased use of the best existing tools are essential if we are to win the battle against the world's deadliest parasite. The world has united in an effort to defeat malaria, but we are still far short of the massive all-out global effort that is required.

The challenge for MMV is to drive forward the discovery and development of new drugs to cure malaria while helping to facilitate the creation of sustainable systems to deliver them to the most vulnerable. A future without malaria is within our reach. ■

### MMV's aspires to develop

- Antimalarial treatments for USD 1 or less
- Medicines for high risk groups such as children and pregnant women
- At least four new ACTs approved by international regulatory authorities before 2010. The first drug could be available for widespread use by 2008
- A one-dose cure
- Access strategies to ensure our products reach the vulnerable

## Innovative Partnerships

### Changing the landscape of neglected diseases R&D

**Product Development Public Private Partnerships (PDPs) are a promising, innovative, and efficient way to develop appropriate drugs for the neglected diseases of the developing world, where the commercial market is usually too small to attract pharmaceutical companies.**

Since 2000, PDPs, in partnership with industry and research institutes, are responsible for the vast majority of the more than 60 neglected disease drug development projects currently underway. MMV, with over 30 projects in its portfolio is considered by many to be one of the most successful PDPs.

### How PDPs work

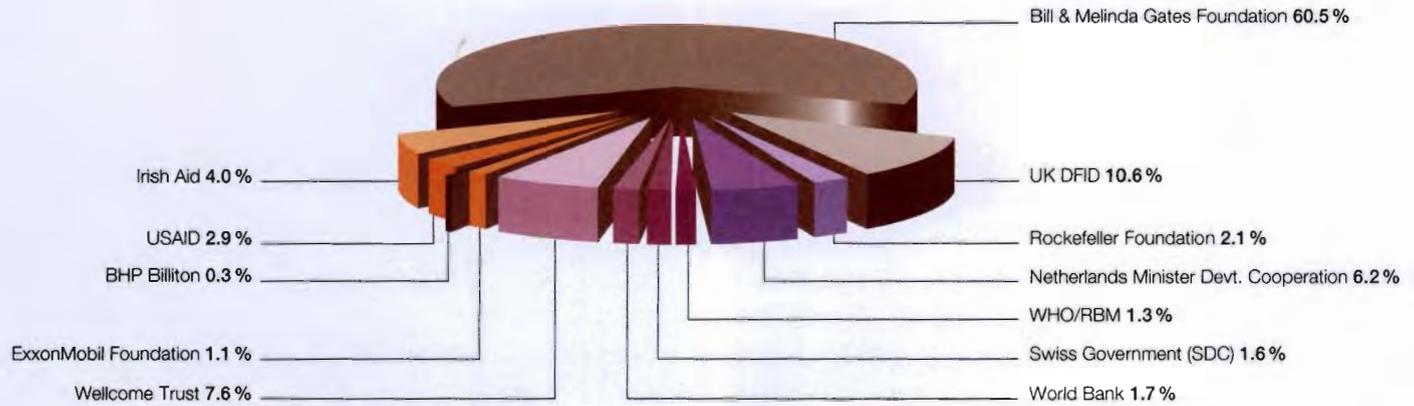
Effective partnerships exploit the best that both the private and public sector can offer. MMV does not conduct drug discovery and development on its own premises. It develops antimalarials by:

- Managing a robust drug development portfolio by attracting and selecting the most promising projects, and terminating projects based on their relative merits
- Allocating philanthropic and public funds to projects from a public health perspective
- Integrating and coordinating multiple industry and academic/public partners and contractors along the drug development pipeline
- Interacting with public sector and endemic-country stakeholders to ensure that the antimalarials MMV develops meet the requirements of, and are accessible to, the millions of people in need ■

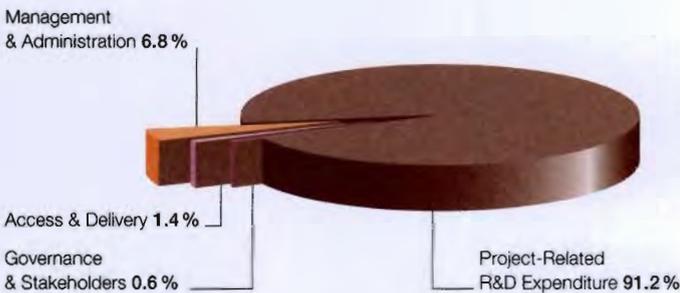


# Focus on Finances

Medicines for Malaria Venture receives funding and support from government agencies, private foundations, international organizations, corporations, and corporate foundations. These funds are used to finance the MMV portfolio of research and development projects to provide new, effective, and affordable medicines to treat malaria. Significant new funding commitments in 2006 from the government of Ireland - Irish Aid, the Netherlands Ministry of Foreign Affairs, and the Rockefeller Foundation augmented the amount of funds pledged from USD 250 million to over USD 273 million to 2010.



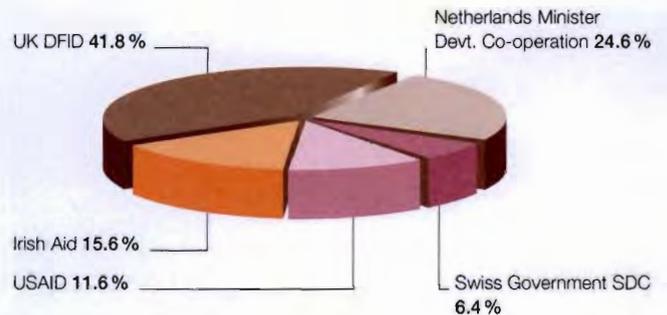
**Figure 1. MMV Funding from 2000-2010** – Since 1999 MMV has received USD 273 million in funds and pledges from 12 donors



**Figure 2. MMV Expenditure 2006** – Total: USD 51.5 million

2006 was a year of active transition for MMV, with far-reaching financial implications. Overall expenditure was up 73% on the previous year. The dramatic increase in R&D expenditure was the result of four projects in late-stage Phase III clinical trials, two new mini-portfolios, and several other new entries into the discovery phase.

As the mission of MMV extended to embrace the facilitation of Access & Delivery of new drugs soon to emerge from the portfolio, USD 0.7 million was allocated to this new item.



**Figure 3. Funding from 5 Government Agencies, 2000-2010** – Total: USD 69 million

**Since 1999, MMV has spent USD 152 million building the largest-ever pipeline of antimalarial drugs.**

**Medicines for Malaria Venture (MMV) is a nonprofit organization created to discover, develop and deliver safe, effective and affordable antimalarial drugs through effective public-private partnerships.**

#### Board of Directors

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#### Expert Scientific Advisory Committee

Win Gutteridge (chairperson), Richard Auty, George Aynilian, Bill Charman, Christine Clayton, David Floyd, Brian Greenwood, Chantal Laburte, David Matthews, Wilbur Milhous, Maria Paris, Meg Phillips, Zul Premji, Ronnatrai Ruangweerayut, Jurg Seiler, Carol Sibley, Bob Snow.

# Delivering MMV's Drugs to Those in Need



MMV has been described  
by the US Institute of Medicine  
as

*“One of the most successful  
public-private partnerships  
involved in neglected diseases  
...one of the main drivers  
of antimalarial drug projects.”*



These are exciting times for MMV. The anticipated emergence of four new fixed-dose artemisinin combination therapies (ACTs) from the MMV pipeline within the next 3 years and the desire to see our drugs have public health impact have motivated us to devise an access and delivery strategy.

A drug must go through a complex discovery and development process before being submitted for stringent international regulatory approval. The next and equally important step is to ensure that the registered drugs reach people who most need them: In the case of malaria, these include children under the age of five, pregnant women, and the rural poor.

The obstacles to overcome are numerous, ranging from the failure of the market to ensure that essential drugs reach those who lack purchasing power, through inadequate market information, weak supply and procurement systems, lack of a properly functioning distribution infrastructure in most malaria-endemic countries, the growing problem of counterfeit drugs, and the need for user-friendly packaging and labelling, to a failure of health systems to look for solutions through the eyes of the underprivileged.

Keeping these issues in mind, MMV has begun to engage with international and national policy-makers, national malaria programme officials, national drug regulatory authorities, and the private sector to better understand the many processes that new drugs need to go through before they reach our target population.

In many African countries, people in rural areas often live beyond the reach of public sector health facilities and have to rely on the private sector for their medicines. In fact, 40-60% of antimalarials are bought from private outlets, where the affordable chloroquine and sulphadoxine/pyrimethamine remain the drugs of choice. Unfortunately, these drugs are increasingly ineffective due to resistance.

MMV's challenge is to look beyond the public sector and find ways to displace these increasingly ineffective drugs with our ACTs.

As a first step, MMV is building its understanding of endemic-country needs. A pilot project has begun at three sites in Uganda, in collaboration with the Ministry of Health, to gather relevant information, e.g., where people go for treatment, who is selling which drugs, the range of antimalarials (and ACTs) available outside of the urban pharmacies, the cost of these drugs, etc. This is being complemented by a study to understand help-seeking behaviour for fever/malaria. The information will enable us to determine how to responsibly make ACTs accessible to our target population in Uganda, to begin crafting models for other countries.

MMV's access and delivery goals are to ensure swift uptake of our products, increase their reach in malaria-endemic countries, and protect our ACT portfolio from resistance. The ultimate objective is to achieve sustainable impact on public health by maximizing accessibility to, and availability of, our drugs at a price tailored to low-income target populations.

## Access & Delivery Advisory Committee

Awa Coll-Seck (chairperson), Dora Akunyili,  
Joseph Amoussou, Issa Diop,  
Win Gutteridge, Paul Lalvani, P A Narayan,  
Daniel Ngamije, Naawa Sipilanyambe,  
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## Working in Partnership

*“Organizations like MMV represent a new way of doing business that can close the gap (between demand and supply of malaria drugs). This new approach makes the most of the strengths of the private and the public sectors. It lets them work together as partners rather than against each other as competitors. It brings in crucial money and expertise. And it reduces the risk of failure for pharmaceutical companies by giving them access to the best new scientific research.*

*MMV shows how the market can work for the world's poorest people. ”*

*Melinda French Gates, World Economic Forum, 2007*

**Australia** Monash University, Melbourne **Belgium** Institute for Tropical Medicine, Antwerp **Burkina Faso** Centre Muraz, Bobo-Dioulasso / Centre National de Recherche et de Formation sur le Paludisme, Ouagadougou / Nanaro Medical Centre **Cambodia** Ministry of Health Technical Bureau and National Malaria Centre, Phnom Penh / National Center for Parasitology, Entomology and Malaria Control, Phnom Penh / Pailin Referral Hospital **Cameroon** Cameroon Medical Research Centre, Douala **China** Holley Pharm, Chongqing **Colombia** CIDEIM, Cali **Democratic Republic of the Congo** École de Santé Publique, Faculté de Médecine, Université de Kinshasa **Gabon** Hopital Louis Schweitzer, Lambarene **Gambia** MRC Labs, Farafenni / MRC Labs, Fajara **Ghana** Kintampo Health Research Centre / Komfo Anokye Teaching Hospital, Kumasi **India** ISPAT General Hospital, Rourkela / Field Station National Institute of Malaria Research, Indian Council of Medical Research Rourkela / Sri Ramachandra Medical College, Chennai / Wentlock District Hospital, Mangalore / Ranbaxy Laboratories Limited, Haryana **Indonesia** Bethesda Hospital, Tomohon / Jayapura General Hospital / RSUD TC Hillers Jl Wairklau, Maumere **Italy** Sigma-Tau Industrie Farmaceutiche, Roma **Kenya** African Centre for Clinical Trials, Kisumu / Kenya Medical Research Institute - KEMRI, Kilifi / Malaria Public Health & Epidemiology Group, Centre for Geographic Medicine, KEMRI - University of Oxford - Wellcome Trust Collaborative Programme, Nairobi / Institute of Tropical and Infectious Diseases, University of Nairobi **Laos** Phalanxay District Hospital **Mali** Malaria Research and Training Center, University of Bamako **Mozambique** National Institute of Health, Maputo / Manhiça Research Centre, Manhiça **Netherlands** Biomedical Primate Research Centre, Rijswijk **Nigeria** OAUTHC, Ile-Ife / University of Ibadan / University of Nigeria, Enugu **Panama** Instituto Gorgas, Panama City **Philippines** Puerto Princesa General Hospital, Palawan **Sénégal** Service de Parasitologie, Faculté de Médecine, Dakar **Singapore** Novartis Institute for Tropical Diseases **South Korea** Shin Poong Pharm. Inc., Seoul **Spain** GlaxoSmithKline, Tres Cantos **Switzerland** Hoffmann-La Roche, Basel / Mediplant, Conthey / Novartis Pharma / Swiss Tropical Institute, Basel / WHO (TDR), Geneva / RBM Partnership, Geneva **Tanzania** District Hospital and Ifakara Health Research and Development Centre, Bagamoyo / Kivunge Public Health Care Centre / Kisarawe District Hospital **Thailand** AFRIMS, Armed Forces Research Institute of Medical Sciences, Bangkok / BIOTEC, Thailand National Science & Technology Development Agency, Bangkok / Hospital of Tropical Disease, Mahidol University Prob-Pra Hospital, Tak Province / Shoklo Malaria Research Unit, Mae Sot **Uganda** MSF Epicentre, Mbarara **United Kingdom** Bath University / Bioniqs Limited York / GlaxoSmithKline, Brentford / Liverpool School of Tropical Medicine / University of Liverpool / London School of Hygiene and Tropical Medicine / Oxford University / St. George's Hospital / Wellcome Trust Research Institute / York University **United States** Albert Einstein College of Medicine, New York / Broad Institute of Harvard and MIT / Genzyme Corp, Boston / Genomics Institute of the Novartis Research Foundation, San Diego / GlaxoSmithKline International, Philadelphia / Johns Hopkins University / National Institutes of Health (NIAID), Bethesda / Texas A&M / University of California, San Francisco / Sanaria, Washington / Sigma Tau Pharmaceuticals, Gaithersburg / University of Iowa, Iowa City / University of Mississippi, Oxford / University of Nebraska, Omaha / University of Texas Southwestern Medical Center, Dallas / University of Washington, Seattle / WRAIR, Silver Spring **Vietnam** Choray Hospital, Ho Chin Minh / National Institute of Malariology, Parasitology and Entomology, Hanoi **Zambia** Clinical Sciences Department Tropical Diseases Research Centre, Ndola / The Malaria Institute at Macha, Choma.

### Malaria Costs Lives

- One child dies every 30 seconds
- An acute infection can kill a child within 48 hours
- Repeated infections contribute to the development of severe anemia, which substantially increases the risk of death
- Approximately 3.2 billion people – mostly in the poorest countries – are at risk from malaria

### Every year, malaria causes:

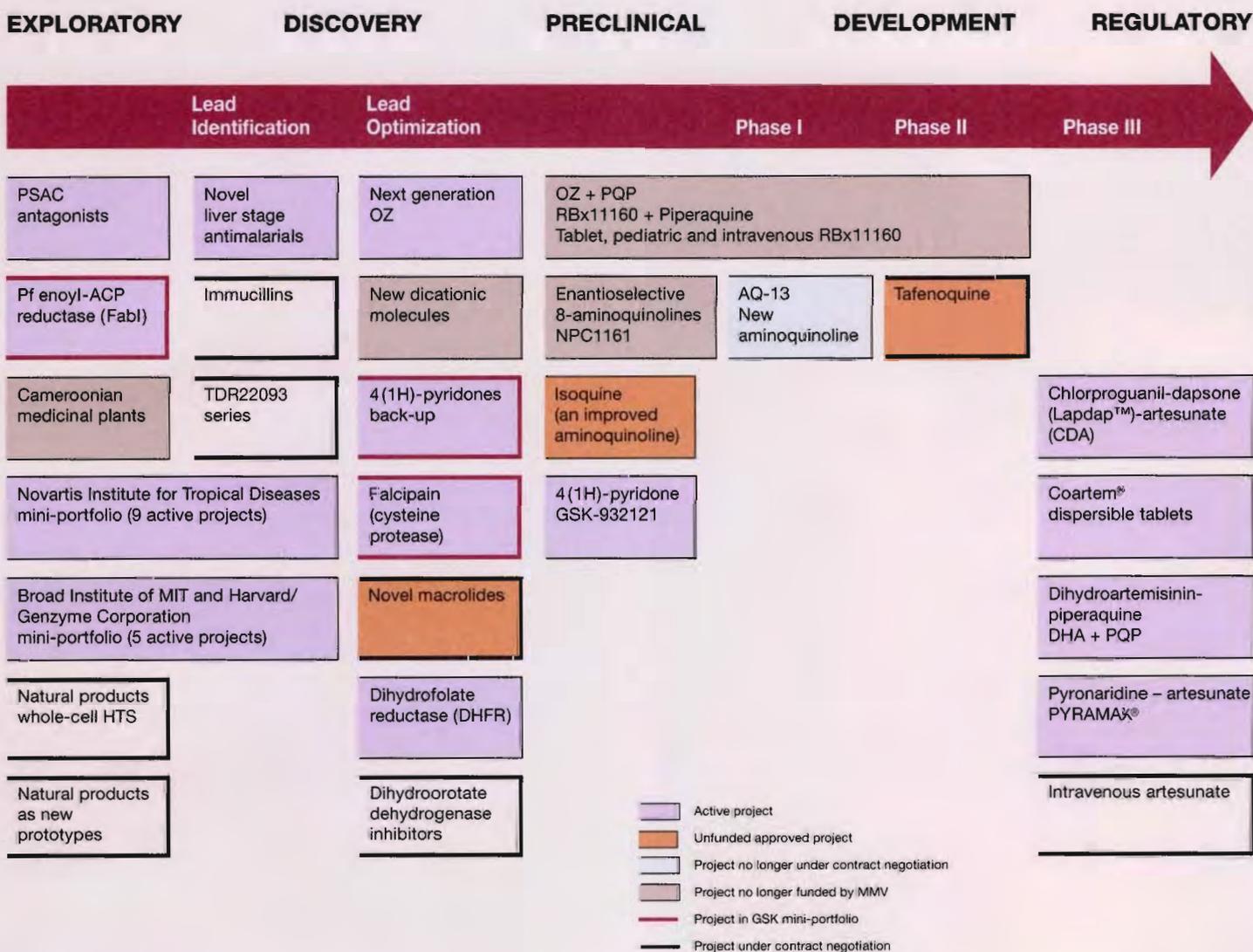
- Over 1 million deaths
- Up to 600 million attacks of acute illness
- Up to 400,000 episodes of severe anaemia in pregnancy
- Up to 300,000 low-birth-weight babies
- Up to 50,000 cases of neurological damage

# MMV Project Portfolio 2007

## MMV's ultimate goal is a one-dose cure

MMV Portfolio priorities focus on delivering products that are appropriate for use in disease-endemic areas. Criteria include:

- Effectiveness against drug resistant strains of *P. falciparum*
- 3-day treatment, or less, to encourage compliance
- Low propensity to rapid emergence of drug resistance
- Safety in small children (<6 months old)
- Intermittent treatments in early infancy
- Safety in pregnancy
- Potential for intermittent treatments in pregnancy
- Treatments suitable for emergency situations
- Treatments against *P. vivax* (including radical cure)
- Treatments against severe malaria
- Transmission-blocking treatments
- Appropriate formulations and packaging
- Affordability to low income populations in endemic countries



*“The global burden of malaria needs to be decreased in order to reach the Millennium Development Goal of reducing the mortality rate among children under five by two thirds by 2015 and to help to achieve the Millennium Development Goals of improving maternal health and eradicating extreme poverty.”*