MMV
Medicines for Malaria Venture

February 1, 2011

Mr Sandy Hollway, AO
Chairman
Independent Review of Aid Effectiveness
GPO Box 887
Canberra ACT 2601, Australia

By email: submissions@aidreview.gov.au

Dear Mr Hollway:

Please find attached our submission to the Independent Review of Aid Effectiveness initiated by the Minister of Foreign Affairs of Australia. This submission is made on behalf of the Medicines for Malaria Venture (MMV), a not-for-profit foundation based in Geneva, Switzerland.

MMV is a Product Development Partnership (PDP) charged with developing a pipeline of anti-malaria medications for the developing world. PDPs such as MMV use public and philanthropic funds to engage the pharmaceutical industry and academic research institutions in undertaking R&D for diseases of the developing world that they would normally be unable or unwilling to pursue independently, without additional incentives. MMV is funded in large part by the Bill and Melinda Gates Foundation, the Wellcome Trust, UK DFID, Spain, and USAID among others.

To date, MMV has been successful in supporting the development and registration of the first paediatric artemisinin combination treatment (ACT) for malaria and an injected drug for the treatment of severe malaria. Over the last 20 months, 53 million courses of this paediatric medicine developed with MMV support have been delivered into Africa. In addition, MMV has developed a strong pipeline of follow up drug candidates, focusing on drugs to address the vivax strain of malaria which is prevalent in Asia Pacific, drugs with better pharmacokinetic and safety profiles and drugs which have the potential to be active against the strains of parasite recently identified in South-East Asia which show reduced susceptibility to current standard of care. Much of this work has been conducted at Monash and other Australian universities, supported by MMV.

As one of the lead PDPs globally, MMV encourages the Review Panel to consider extending its funding to include clinical development activities using this type of public/private, not-for-profit partnership in order to increase funding effectiveness, efficiency and impact. Specifically, MMV asks the Review panel to consider the following:

1. That Australia can have a significantly greater impact on developing world health issues if it expands its mandate to support clinical trials in developing world infectious diseases in order to bring to patients safe, effective and affordable medicines.
2. That the risk of such an investment can be mitigated by supporting those clinical trials through PDPs, which have an excellent performance record, have international credibility, transparent and tight fiscal management, and operate in the public interest.
3. That the medical and research oversight in Australia's interest can be overseen by NHMRC, which has the expertise and administrative structures in place to guarantee the quality and medical robustness of these trials.

It is the position of MMV that supporting such a program will leverage Australia's scientific and medical expertise and deliver demonstrable impact for Australia's taxpayers without requiring significant new administrative and bureaucratic structures. This "whole of government" approach can engage several branches of the public service, leverage the expertise of each, and capitalize on efficiencies.

Further, given the recent statement by the Director General of the World Health Organization (WHO), Margaret Chan, the WHO executive board is reviewing a proposal for a reduced WHO budget. In her comments, Dr. Chan highlighted that it was "critical to avoid duplication with public private partnerships, as well as various charities, foundations and donor governments." These remarks highlight the increased expectations and responsibilities placed on PDPs.

Today, Australia is recognised as a leading political and economic figure, with growing economic interest abroad, particularly in the Asia Pacific region. In keeping with its expanding international position and its commitment to the Millennium Development Goals, MMV encourages the Review Panel to consider expanding AusAID's remit to include supporting clinical development activities through the funding of PDPs such as MMV. We thank you in advance for considering our submission and remain at your disposal should you have any questions.

Kind regards,

David Reddy PhD
Chief Executive Officer, MMV
reddyd@mmv.org

OIL SEARCH LIMITED
(Incorporated in Papua New Guinea)
ARBN – 055 079 868

1 February 2011

Mr. Sandy Holloway, AO
Chairman
Independent Aid Effectiveness Review
GPO Box 887
CANBERRA. ACT. 2601

Dear Mr. Holloway

MMV SUBMISSION TO INDEPENDENT AID EFFECTIVENESS REVIEW

On behalf of Oil Search Limited (OSL), I would like to register my full endorsement of the submission lodged by Medicines for Malaria Venture (MMV) to the Aid Effectiveness Review.

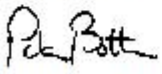
Oil Search has an operating history in PNG spanning more than 80 years and is perhaps more fully aware of the wide-ranging, damaging impact of malaria on its operations and the related communities than any other Australian corporate entity operating in PNG.

We have had a professional association with MMV since the May 2008 inaugural business mission to PNG, organised by Business for Millennium Development to which OSL is a member and upon whose Board of Directors I sit, along with Tim Costello and Simon McKeon. Over the past two and a half years, we have engaged in a range of collaborations with MMV around our PNG operations and hold them in the highest regard.

OSL is a strong supporter of the need to develop new drugs and medicines clinically tested within the impacted countries to combat the endemic infectious diseases, particularly TB, malaria and increasingly HIV/AIDS within PNG. We believe it is a totally appropriate policy initiative for the Australian Government to expend some of its current and anticipated greatly increased ODA, supporting well designed clinical trials conducted at western world standards which also enhance local healthcare capability.

If any additional discussion about the relationship between OSL and MMV or our views on infectious diseases within PNG would be beneficial, I would be pleased to discuss this further with members of the Aid Effectiveness Review panel.

Kind regards



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February 2011

Mr Sandy Hollway, AO
Chairman
Independent Aid Effectiveness Review
GPO Box 887
CANBERRA, A C T 2601

Dear Mr Hollway,

Re: MMV Submission to Aid Effectiveness Review

It is my honour to provide this letter of endorsement for the MMV submission to the Aid Effectiveness Review being conducted by the Australian Government through the Foreign Minister's office.

I have been very actively involved in several of Product Development Partnerships established to develop new vaccines, drug products, medical diagnostic devices and microbicides to combat the most serious developing world infections diseases. As you might already be aware, I have first hand knowledge about the effectiveness of the PDP virtual pharmaceutical business model through my Chairman role for the Malaria Vaccine Initiative. The fact that all 17 PDPs are dominantly funded by the Bill and Melinda Gates Foundation represents an important endorsement of their effectiveness.

As an unofficial spokesperson for the Australian scientific community, there is no doubt about their strong support for the need to develop new vaccines, drugs and diagnostic tools which are clinically tested within those impacted countries where the endemic infectious diseases exist. PNG is one of these most impacted countries. The Australian medical science community focused on infectious diseases believes it is a totally appropriate policy initiative for the Australian Government to expend some of its current and anticipated greatly increased ODA supporting well designed clinical trials conducted at western world standards which also enhance local healthcare capability.

I would be pleased to discuss the basis of my support for the MMV submission in more detail with members of the Aid Effectiveness Review Panel should this be of interest.

Yours sincerely,

Sir Gustav Nossal AC CBE
Professor Emeritus
Department of Pathology
The University of Melbourne
Victoria 3010

Submission to Independent Review of Aid Effectiveness

This submission is lodged by Medicines for Malaria Venture (MMV), a Swiss-based international not-for-profit organization that is one of several global product development partnerships that develops high quality and affordable medical products for the developing world.

Overview:

The Australian government should expand its policies for Overseas Development Assistance (ODA) with a particular focus on the health of the populations in its sphere of concern, including Papua New Guinea, Indonesia, Asia Pacific and Africa. These concerns especially include the future treatment and prevention of malaria, tuberculosis and HIV, among other major infectious diseases. Focusing on the delivery of today's medicines, while critically important, is insufficient to counter the threat of drug resistance emerging throughout the world, and, in the case of malaria, specifically in the Asia Pacific region. Australia has a critical gap in its aid effectiveness: it is not looking to the future health needs of the developing world. The inability to control infectious disease precludes the ability of the world to achieve the Millennium Development Goals.

To fill this gap, Australia can create the policies and programs to support the development of new medicines and preventative health treatments for currently entrenched and newly emerging infectious diseases. In particular, it should support clinical trials of new health products for the developing world.

While delivery of current health solutions is critically important, that sole focus is not in Australia's long-term interest. A move into the funding and oversight of developing innovative health tools, e.g. through supporting clinical trials, is a natural progression of Australia's early-stage research excellence and will use the country's recognized capabilities to benefit vulnerable populations in the developing world. The focus on health solutions for the future will also be crucial for the industries that sustain Australia's growth and continued prosperity, most notably the mining sector, which is increasingly working in the Asia Pacific and African regions. International development, one of the objectives of Australia's ODA strategy, relies on commerce to create the wealth and jobs that will end poverty. As an international donor, Australia can work with public-private partnerships and win a competitive edge by tailoring new goods and services specifically designed to meet the needs of poor people.

It can do so with limited risk and high return by having these clinical trials conducted by Product Development Partnerships (PDPs)—global not-for-profit entities that leverage private and public funds and expertise to develop high quality, affordable health products for the developing world. These PDPs have an established track record of impact and achievements, strong governance, and tight fiscal management. Further, they collaborate extensively with governments, global health experts, scientists and major international industry partners.

In order to leverage Australia's own skills and expertise, it can fill its current gap in clinical trial oversight with expertise from the National Health and Medical Research Council (NHMRC), which has solid experience in supervising clinical trials. A wealth of preclinical infectious diseases expertise exists in Australia's universities and other entities that can be harnessed for global public good through Australia's private sector.

This submission is supported by the following attachments:
Attachment 1 The PDP Model – Description and independent assessments
Attachment 2 PDP Case Study - Medicines for Malaria Venture (MMV)
Attachment 3 Australian Malaria Expertise and NHMRC Funding
Attachment 4 Further Reading

Response to terms of reference:

MMV's submission addresses below each of the individual terms of reference for the Aid Effectiveness Review.

1. Appropriate geographic focus

Current focus on Asia Pacific is appropriate, with special focus on those areas with high infectious disease rates. This is especially important in the case of malaria, given that the World Health Organization has identified the Cambodia/Thailand/Myanmar border as a particular hotspot for the development of resistance to artemisinin (a gold-standard antimalarial medicine) in the malaria parasite.

With increase of funds expected in future years for AusAID, assistance to Africa should increase where the burden of infectious disease is also very high.

These are also areas of great concern for Australia's mining sector, which is working overseas in PNG, Indonesia, and increasingly in Africa.

Absorptive capacity of bilateral aid will continue to be a challenge for governments, thus Australia's focus should be on working with effective NGOs that have global reach and are capable of managing significant tranches of funds in an open, transparent and effective manner.

Clinical trials in areas such as those in PNG, where PDPs currently operate in collaboration with local partners, will help create the next generation of safe, effective, and affordable medical treatments. In the case of malaria, since resistance to the frontline treatment, artemisinin, has been confirmed in the region of Cambodia/Thailand/Myanmar, clinical trials in the region are critical to the development of the next generation of cures.

In malaria-endemic Africa, PDP networks are particularly wide-reaching, strong, and efficient. Thus, for example, 53 million doses of a new MMV-supported pediatric medicine have been dispatched to children in 33 countries in the 20 months since it was launched. These networks have strong relationships with doctors, hospitals, and community health structures at grassroots level, as well as health ministries at government level. Australia could cover its current gap in aid capacity in Africa by investing in clinical trials with PDPs and extend its reach throughout the continent.

2. Appropriate sectoral focus

It is best if the sectoral focus for overseas development is not rigidly prescribed, as needs by country and region will differ. However, to contribute to the achievement of the Millennium Development Goals as pledged, Australia needs to increase its expenditure on the documented health threats that imperil the developing world.

Australia can achieve this by leveraging its current national and international expertise in early-stage research, and bolstering the capacity of the country to provide medical solutions to the developing world. The involvement of NHMRC, which currently oversees clinical trials, would

be a good example of cross-public service leverage. NHMRC could create a dedicated fund for the clinical trials with reporting to AusAID.

Australia is among the world's leaders in malaria preclinical research. It also has very strong preclinical research capacity in other infectious diseases (e.g. dengue). However, this "bench research" from Australia's world-class education sector has not translated adequately into the actual medicines and other products that will save lives.

Part of the issue is the slow-moving transfer of knowledge between the education sector, the health sector, the pharmaceutical industry, and the overseas development sector. There is currently no policy framework to enable AusAID to assist in the transfer of knowledge to medical products, nor is there expertise within AusAID to oversee such life-saving work.

By allowing AusAID to work with PDPs, much of this fragmentation of knowledge can be addressed, as PDPs work and share know-how across all sectors for development of health solutions. PDPs uniquely span the gap between early-stage laboratory research through later-stage manufacturing with pharmaceutical companies. They also work with government health ministries on policies for delivering solutions, and other NGOs and civil society organizations to ensure access to high-quality affordable medicines.

AusAID's current focus on health-systems strengthening and capacity-building is consistent with the work of PDPs in conducting clinical trials and assuring access to life-saving medicines.

3. Distribution to low- and middle-income countries

Infectious diseases affect both low- and middle-income countries, but as with most medical issues, countries with stronger health systems have better access to treatments. Regardless of the income level of the country, clinical trials need to be conducted in the areas where the diseases are found. Thus, PDPs work across the developing world, including throughout Africa and Asia Pacific.

In malaria, for example, the two dominant strains of the infecting parasite, P. *vivax* and P. *falciparum,* can be found in PNG, an unusual demography that puts the population under continued health risk and requires new approaches to treatment. In the Cambodia/Myanmar /Thailand border area, where the WHO has identified the emergence of artemisinin-resistant strains of parasite, the world needs to find alternative treatments that are going to be effective for these populations once resistance well and truly sets in. In Africa, where the deadly strain of P. *falciparum* claims the lives of as many as 800,000 children per year, new forms of pediatric treatments are urgently needed.

4. Relative costs and benefits of forms of aid

With its increase in available funds for aid, Australia is positioned to have more influence in the international donor community. Australia should continue to provide support for both bilateral and multilateral funding.

At the same time, an increased share of the aid budget should be directed to those NGOs with particular characteristics: the NGOs must be capable of absorbing and making effective use of large tranches of funding; they should be trusted by other global donors; and they must be able to provide evidence of their effectiveness and efficiency. This will allow Australia to continue to emphasize its own global aid priorities while ensuring that such aid is having the desired impact.

PDPs, which are currently funded by the UK DFID, USAID, the Bill and Melinda Gates Foundation, The Wellcome Trust, Spain and others can effectively use funds that are directed by Australia, and can do so in concert with other donor monies as well. PDPs manage over 40% of global grant funding for neglected disease research and development. Very low administrative overheads of these organizations, many of which conduct "virtual" product development also mean that they are an efficient use of taxpayer money.

An additional efficiency is through the leverage that PDPs provide. As public-private partnerships, PDPs also leverage private in-kind contributions that often provide more than a 1:1 match in funding vis-a-vis donor funds.

5. Performance of the aid program; lessons learned in aid effectiveness

Australia has done a great deal to improve its aid effectiveness, including creating proper oversight mechanisms. In order to increase its effectiveness, Australia needs to ensure a focus on continuous improvement, and benefiting from the lessons already learned by other major donors who are working for similar ends.

6. How can the program increase its effectiveness?

Australia can increase its effectiveness by being forward-looking, expanding its scope to include the development of solutions for emerging health problems; partnering with NGOs that can leverage a considerable range of expert relationships, including from the private sector; and using a "whole of government" approach to its funding. Putting in place mechanisms to reduce risk and increase transparency would also help effectiveness.

In this way it can, quickly and efficiently, achieve the following benefits:

- Contribute to the MDGs by supporting not only current health solutions but developing much-needed next generation solutions, particularly through supporting clinical trials of infectious diseases
- Partner with internationally-respected NGOs that leverage private sector knowledge and funding for the public good
- Leverage globally-respected Australian scientific expertise in infectious diseases
- Disburse large tranches of project funding to organizations that can not only absorb the funds but also have well-established and efficient global oversight mechanisms in place
- Take advantage of already-established skills across the public service by partnering with the health sector of the Australian government
- Focus in areas of substantial economic interest to Australia's overseas industries, including the mining industry

- Leverage the strong existing NGO networks in Africa and parts of Asia Pacific, from both the grassroots up, and the health ministries down
- Leverage the capacity-building effects of the clinical trial procedures in the developing world, including the training of health workers and hospital/laboratory infrastructure improvement
- Create important health products that are visible successes for the Australian taxpayer.

7. ***Future structure of the aid program, coordination across the public service and coordination across donors***

Coordinate with already extant donors groups such as the PDP Funder's Group—a network of many of the world's donor governments and philanthropists, chaired by the UK Department for International Development (DFID). The group shares knowledge and expertise and is working to reduce the administrative burden for both donors and recipients. The group works together to be continuously more efficient with donor and taxpayer funds.

Coordinate between NHRMC and AusAID to provide appropriate scientific and medical input to clinical trials. Other areas of possible coordination across the public service could be explored.

8. ***Strengthening evaluation of the aid program***

The aid program has good evaluation mechanisms in place.

They could be strengthened by working with other organizations that also conduct evaluations. For example, PDPs regularly undergo monitoring from donors such as the PDP Funders Group, individual donors, and non-profit organizations such as the Sydney-based Policy Cures Institute that regularly reviews the entire PDP sector.

9. ***Managing fraud and risk***

Australia can limit the risk of financial fraud by:

- Keeping oversight mechanisms in place through its already-developed procedures
- Providing funding to organizations that have established experience in working effectively in high-risk areas, and that have strong governance in place.
- Working with organizations that have strong contractual and partnership skills.

Australia can limit its risk of project failure by providing funding for projects where earlier funders have already invested. For example, much of the early risk of health product development—university and early-stage research—has been absorbed by funders such as DFID, The Wellcome Trust, and the Bill and Melinda Gates Foundation.

Conclusion

MMV strongly recommends that Australia collaborates with Product Development Partnerships, supporting the discovery, development and delivery of innovative health technologies by harnessing the global network of PDP private and public expert partners. Collaborating with PDPs and teaming up with NHMRC and other Australian bodies offers the following benefits:

- Provides documented evidence of improved health outcomes in the developing world
- Allows investment in global non-governmental organizations with a proven record of achievement, strong governance, and tight fiscal management that work with governments, international health experts, scientists and major international industry partners. In 2008 US $2.96 billion was spent on neglected disease research and development of which PDP's managed 19.6% of total funding
- Provides a structure that brings together unique capabilities provided by public partners, donors and the private sector
- Capitalizes on established relationships and procedures to coordinate ODA across donor organizations

Although it is not part of the explicit Australian aid program review criteria, other benefits would accrue to this proposed structure. Australia could:

- Strengthen its own internal capacity for late-stage development of health products, building on the nation's global position in early-stage medical research
- Protect its future long-term security and economic interests by tackling health issues that have the potential to impact the Australian population, particularly given its proximity to disease-endemic regions
- Maximize effective partnerships with global industries, especially mining companies, which are substantially affected by the burden of infectious diseases in the areas where they operate
- Leverage the effectiveness of the Australian taxpayers' money by investing in the less risky, later phases of development as the earlier, more risky phases have already been supported by other global donors over the past 10 years.
- This in return would allow the Australian taxpayers to witness significant, tangible benefits within a short three-to-five year timeframe

Attachment 1: The PDP Model – Description and independent assessments

In the late 1990s an innovative collaboration model for development of medical solutions for neglected diseases emerged in the form of public-private partnerships known as "product development partnerships" (PDPs). These PDPs were created from a need to generate innovative approaches to alleviate the global burden of neglected diseases by taking the expertise and knowledge of both the private and public sectors, and exploiting each of their strengths to find the most efficient and effective solutions.

PDPs address the lack of commercial incentive to undertake the cost of development for vaccines, diagnostics, and drugs for neglected diseases of the developing world. They use public and philanthropic funds to engage academic research institutions and the pharmaceutical industry in undertaking development of solutions for diseases of the developing world that these institutions would normally be unable or unwilling to pursue independently, without additional incentives. The specific objectives of individual PDPs vary, but the basic mission is the same: to develop products for use as a public good to address the health needs of vulnerable populations in the developing world.

The sections below provide insights on PDPs from the World Health Organization, UK DFID and the Sydney-based Policy Cures Institute

The World Health Organization states:

> *Overall, product development partnerships score very highly on developing country impact because of their focus on developing affordable suitable products for developing country use; their routine practice of working with developing country researchers and developers; and, to varying degrees, their capacity building efforts in developing countries. Donors are increasingly favouring product development partnerships as their vehicle of choice to disburse neglected-disease funding, while smaller donors may disburse virtually all their funding in this manner (likely reflecting the ability of product development partnerships to minimize donor management needs). The product development partnership route offers high developing-country health impact and operational efficiency, and is the only mechanism that successfully stimulates early and ongoing involvement of multinational corporations. The PDP acts as a facilitator and catalyst, bringing dedicated sources of funding and know-how to committed professionals so they can collaborate on the right projects to fulfill the objectives of the PDP's mission.*

Public health, innovation and intellectual property:
Global strategy and plan of action
Report of the Expert Working Group on
Research and Development Financing
World Health Organization
Sixty-third World Health Assembly
8 April 2010

UK DFID in its framework review regarding malaria also found a positive impact of PDPs:

> *Malaria product innovation, particularly for drugs, has evolved significantly in recent years. Product development partnerships (PDPs), such as the Medicines for Malaria Venture and Drugs for Neglected Diseases Initiative, have brought together pharmaceutical industry expertise with public financing and a focus on the needs of developing countries. This has resulted in an accelerated development and the approval of new ACT formulations, including child-friendly products. Product development partnerships have also been established to accelerate the development of malaria vaccines (Malaria Vaccines Initiative) and new insecticides for vector control (Innovative Vector Control Consortium).*
>
> *The product development partnership model has provided an important means to incentivise and accelerate technology development for product markets that may not otherwise be commercial priorities. Other approaches, such as market based incentives to encourage greater private sector investment in malaria product development and to strengthen R&D in malaria endemic countries, should be explored to complement investments in PDPs.*

Breaking the Cycle: Saving Lives and Protecting the Future
The UK's Framework for Results for malaria in the developing world
December 2010
www.dfid.gov.uk/Documents/publications1/prd/malaria-framework-for-results.pdf

The independent Sydney-based Policy Cures Institute did an analysis in 2010 of the role PDPs in research and development for neglected diseases. Their published report stated the following:

> *Despite their relatively young history, PDPs now occupy an important place in the global R&D landscape for neglected diseases. In 2007, they collectively attracted 42.0% (US$465 251 887) of global external funding for neglected diseases (excluding NIH funding) and nearly a quarter (23.1% or US$469 392 952) if NIH is included. This success can be explained by various factors. The PDP business model can be very attractive to funders, in particular small to medium size funders. In general, PDPs select, manage and terminate projects and partners within the overall product portfolio, rather than requiring funders to make these choices. This reduces the management load on smaller funders. For instance, Irish Aid explicitly mentioned the low management responsibilities associated with PDPs as a reason for choosing this channel for future increases in aid flows. It also greatly mitigates the risks they are exposed to as highly technical scientific decisions are made by PDPs in consultation with their Scientific Advisory Committees, who advise on the selection and scientific merit of projects to be funded and progressed, rather than by funders who maybe less familiar with the complex, multi-million dollar scientific choices involved.*
>
> *Financial risk is also greatly reduced since, under the PDP model, investments are made by multiple funders into portfolios of multiple projects. This means that failure of one lead or product does not mean a funder's investment is wasted,*

since funds can be rapidly shifted to other more promising projects within the portfolio. The portfolio approach is also more resilient, since a sudden decrease or withdrawal of funding by one donor does not necessarily have a fatal impact on the R&D programme, thus also protecting the investment of other funders. By contrast, the model under which funders choose individual projects to invest in (sometimes called 'picking winners') has a higher risk for both the funder and the science: the former, if the project fails; the latter if the funder withdraws their support for the project, at which point it dies or goes on the backburner, no matter how promising it might be.

Effective PDPs – we note that not all PDPs are equally effective – also offer excellent health returns on investment, since they have lower R&D costs than the private sector model. This is due partly to their lower cost of capital (PDP funds come mainly from the public and philanthropic sectors rather than the stock market) but also their ability to leverage in-kind contributions, and to build partnerships that maximise efficiency by using each R&D player in their area of comparative advantage (e.g. industry groups working on medicinal chemistry; academic groups providing disease expertise in clinical trial design; developing country manufacturers providing lower-cost scale-up and manufacturing expertise).

M. Moran, J. Guzman, A.L. Ropars, A. Illmer,
"The role of Product Development Partnerships in research and development for neglected diseases"
International Health 2 (2010) 114–122

Attachment 2: PDP Case Study - Medicines for Malaria Venture (MMV)

Mission: Discover, develop and deliver safe, effective and affordable antimalarial drug products to treat and protect people most at risk of malaria infection. Also, influence, innovate and integrate to provide public health community most appropriate tools to achieve maximum public health impact and malaria drug uptake effectiveness.

Impact: To date, MMV has registered two medicines—an intravenous form of artesunate for treatment of severe malaria, and Coartem® Dispersible, a pediatric formulation developed in partnership with Novartis. Since this formulation was made available in late 2009, **53 million doses have been delivered for children in 33 countries.**

History: Founded in 1999 by WHO/TDR, IFPMA, World Bank, donor governments, research partners and philanthropic foundations. MMV is a Swiss not-for-profit operating as public-private partnership.

Business Model: MMV partners with a broad range of research entities and pharmaceutical firms spending 80% of its typical USD 55 million annual budget on product development. These funds typically attract an approximately1:1 matching "in-kind" contributions by its research and pharmaceutical partners. From 1999 to 2010 MMV mobilized over $US480 million in support of its research, management and access work.

Governance Model: Comprises a set of integrated mechanisms including Board of independent non-executive Directors (Expert Science Advisory Committee, Safety Advisory Committee, Access and Delivery Advisory Board, annual audited financial reports and published *ad hoc*, periodic reviews by external, independent NGOs and major funders).

Partnerships: Over 130 partnerships in 45 countries including Africa, Asia Pacific, US, Europe)

- **Australia**: Over USD $9m invested 2000 – 2010 funding R&D projects at eight institutions (Monash University, QIMR, Australian Army Malaria Institute, Eskitis Research Institute Griffiths University, Alfred Hospital, Royal Adelaide Hospital, Darwin University, Melbourne University), APPMEN – Asia Pacific Elimination Network
- **Other Asia Pacific:** Research and clinical trial partners in 13 Asia Pacific countries Cambodia, China, Hong Kong, India, Indonesia, Laos, New Zealand, Philippines, PNG, Singapore, South Korea, Thailand, Vietnam
- **Africa:** Clinical trials conducted in 15 African countries (Benin, Burkina Faso, Gabon, Gambia, Ghana, Ivory Coast, Kenya, Malawi, Mali, Nigeria, Mozambique, Senegal, Tanzania, Uganda, Zambia)
- **APMEN**: MMV is an active member of the Asia Pacific Malaria Elimination Network established in 2009. APMEN is a cohesive network of national and international public health professionals with interest and skills in malaria research and elimination in the Asia Pacific region.

Drug Development Costs and Comparison: MMV built the largest malaria drug pipeline in history comprising almost 60 projects. All this has been accomplished in 11 years. MMV is extremely cost-effective when compared to conservative industry estimates of $800 million to develop one new chemical entity through clinical trials and market launch.

Attachment 3: Australian Malaria Expertise and NHMRC Funding

Overview: Australian R&D institutions have a long history of malaria research with many researchers widely recognized as among the global leaders (see below). However, almost all malaria drug development has been restricted to the preclinical research phase due in large part to the historic lack of developing world infectious diseases clinical trial funding opportunities based on existing Australian government policy.

R&D Grants History 2000 – 2010: Over the 11 year period 2000 – 2010 NHMRC funded a total of AUD $90.35 million. Over this period 203 malaria research grants were made to a total of 21 Australian research institutions, representing about 2% of total research grants. Since 2000 the annual amounts and number of grants has risen from $1.8 million over 26 grants (avg $70k per grant) to $15.4 million over 71 grants (avg $216.4k) in 2010.

Australian Research Institutions Funded: Importantly, the seven institutions below with at least 12 grants each received a total of 158 grants. Although they collectively represent only 33% of total grant recipient institutions by number, they received 78% of total grants awarded. This indicates deep malaria expertise exists at the seven institutions shown below which are shown with their related number of grants.

- 57 Walter and Eliza Hall
- 22 Queensland Institute of Medical Research
- 21 University of Melbourne
- 16 ANU
- 16 Monash University
- 14 LaTrobe University
- 12 Menzies School of Health Research

Australian Malaria Scientific Expertise: Australia's depth in malaria research and development expertise is among the most extensive worldwide outside the pharmaceutical sector. This depth is demonstrated by both the number of malaria scientists with international reputations and the significant number and geographic distribution of research institutions which employ them. To illustrate this expertise, a partial list of some of Australia's most recognised global malaria experts totaling 26 and their 14 related hosting institutions has been compiled below:

- ***ANU:*** Prof Kiaran Kirk
- ***Australian Army Malaria Research Institute***: Prof. Denis Shanks
- ***Burnet Institute***: Prof Brendan Crabb; Prof John Reeder
- ***Eskitis Institute***, Griffith University: Prof. Ron Quinn; Prof. Vickie Every
- ***Foursight Associates***: Dr. Graham Mitchell
- ***James Cook University***: Prof Tom Burkot; Prof Scott Richie
- ***LaTrobe University***: Prof Leann Tilley; Emeritus Professor Robin Anders
- ***Melbourne Univeristy***: Prof. Geoff Mc Fadden; Prof. Malcolm McConville
- ***Menzies School of Health Research***, Darwin University: Prof Nick Anstey, Prof Rick Price
- ***Monash University***: Prof Ross Coppel; Prof. Bill Charman; Prof. Sue Charman

- ***Nossal Institute of Global Health***: Professor Emeritus Sir Gus Nossal, Prof. Graham Brown
- ***Queensland Institute of Medical Research***: Prof. James McCarthy; Prof Maxine Whittaker
- ***University of Western Australia***: Prof Tim Davis
- ***Walter and Eliza Hall Institute***: Prof Alan Cowman; Assoc. Prof Louis Schofield, Dr. Ivo Mueller

This list is exemplary only and does not purport to include all the malaria research experts in Australia.

Overseas Clinical Trial Funding History: Over the period 2000 – 2010 NHMRC funded nine overseas clinical trials totaling AUD $8.75 million across seven Asia Pacific countries comprising Indonesia (2), Thailand (1), Vietnam (1), Sri Lanka (1), PNG (2). One trial's location is not available.

NHMRC Funded Asia Pacific Health Research: NHMRC has a demonstrated history of sponsoring global health research in collaboration with overseas specialists. The most recent examples are the 19 health projects presented at NHMRC's 2010 conference "Global Health – addressing the health needs of the Asia Pacific region". These projects were conducted at a total of 14 Australian universities and other research entities plus their Asia Pacific partners in PNG, Laos, India, Vietnam plus countries within the South Asian Clinical Toxicology Research Collaboration Unit.

NHMRC Medical Endowment Scheme: This scheme, which is unique to NHMRC among Australian government departments, provides NHMRC with the capability of sourcing funds from non-government entities and using them across financial years. This is particularly important to provide the required flexibility for clinical trial funding due to their normal duration and timing.

Attachment 4: Additional reading:

Independent evaluations of MMV

- MMV Organizational Report by FasterCures (November 2009) http://www.mmv.org/newsroom/publications/medicines-malaria-venture-organizational-report

- World Bank Global Program Review (June 2007) http://www.mmv.org/newsroom/news/world-bank-global-program-review-gpr-published

- Positive Independent Donor Review of MMV (May 2005) http://www.mmv.org/newsroom/publications/positive-independent-donor-review-mmv

For further information about MMV please visit: www.mmv.org

External reports on malaria financing

- Breaking the Cycle: Saving Lives and Protecting the Future - The UK's Framework for Results for malaria in the developing world (December 2010) http://www.mmv.org/newsroom/publications/breaking-cycle-saving-lives-and-protecting-future

- Financing Mechanisms for Malaria (February 2010) http://www.mmv.org/newsroom/publications/financing-mechanisms-malaria

- Neglected Disease Research & Development: New Times, New Trends The second G-FINDER report from The George Institute for International Health (December 2009) ¨ http://www.mmv.org/newsroom/publications/neglected-disease-research-development-new-times-new-trends

- Case Studies for Global Health (October 2009) http://www.mmv.org/newsroom/publications/case-studies-global-health

- Wellcome Trust: The new landscape of neglected disease drug developmentL http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_publishing_group/documents/web_document/wtx026592.pdf