

## Senate Foreign Affairs, Defence and Trade References Committee Inquiry into bilateral aid to Papua New Guinea

### Submission by Medicines for Malaria Venture (MMV)

30 March 2015

#### Summary

*The Australian government, through the Department of Foreign Affairs and Trade provides valuable overseas aid to alleviate poverty and promote economic growth. Australia is jointly leading the global push to eliminate and ultimately eradicate malaria in the Asia Pacific Region.*

*In nations where communities are geographically inaccessible, malaria elimination will require the continued development of health, education and community infrastructure. The current GMAP<sup>1</sup> four-stage process initially focuses on scaling up for impact, then sustained control, followed by pre-elimination leading to elimination. How quickly countries can progress through these stages is directly linked to continued development of health, education and community infrastructure. Achieving accelerated malaria control provides a strong base to enable a well-informed review of pre-elimination scope, timing and cost.*

*In nations such as PNG mechanisms are needed to link human development and economic growth, and Australia's aid program can assist in this process. Support for malaria elimination should help accelerate regional economic growth and social development. Improved community access to medicines, skilled resources and sustainable health capability will be critical to achieving the twin goals of sustainable economic and human development.*

*The elimination of malaria in PNG will require a commitment by PNG, provincial and regional authorities along with ongoing support from global and bilateral partners.*

*For over 15 years Medicines for Malaria Venture (MMV) has been developing a pipeline of new medicines to treat and prevent malaria, thanks to contributions made by international philanthropic, industry and government supporters. There is a strong role for the Australian aid program to strengthen its support to MMV in the development of new and effective malaria medicines. This should include strong support to PNG to assist the nation to accelerate strategies for malaria control, pre-elimination and elimination.*

#### Recommendations

1. Aid for PNG should be sustained, in a way that is consistent with Australia's political, economic and social objectives. Aid should target areas such as health and education, and mechanisms that will promote sustainable economic growth and human development. The government's support for health systems strengthening in PNG will be critical to improvements in health.
2. Towards this end, the Australian government should articulate an Aid for Malaria Strategy that outlines priorities and regional strategies to support malaria elimination. The guiding principles of the Global Malaria Action Plan (GMAP), along with commitments to malaria elimination through the Asia Pacific Leaders Malaria Alliance (APLMA), can inform this process. The strategy could explore both PNG's active participation in regional and global programs aimed at accelerating malaria control and elimination as well as Australia's support in this endeavour. This strategy should identify how Australia can assist with the development of

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<sup>1</sup> Global Malaria Action Plan <http://www.rbm.who.int/gmap/1-2.html>

tools and resources, including the development and distribution of new and effective antimalarial medications. Support is required in areas such as policy and regulation, planning, financing, procurement and supply chain management, monitoring and evaluation and research and development including the collection and sharing of drug resistance information across disease networks and borders.

3. Australian aid policy should reflect the important contributions by non-governmental sectors, which are increasingly active in international development cooperation. This includes the philanthropic and private sectors, which offer the potential to make a bigger contribution to the elimination of poverty and to support economic growth through the delivery of “global public goods.” Australian aid should include strong financial and technical support to multilateral organizations such as the World Health Organization, and the Global Fund to Fight AIDS, TB and Malaria, and in particular to regional agencies aimed at strengthening health systems to support malaria control.

4. The Australian aid policy should support the implementation of the recommendations of the APLMA Quality Taskforce (June 2014)<sup>2</sup> in particular to:

- Ensure universal access to quality-assured, affordable antimalarials to treat all confirmed cases of malaria
- Stop production, marketing and use of monotherapies by 2015 and promote the use of Fixed Dose Combinations
- Scale-up use of affordable rapid diagnostic tests, especially in the private sector
- Eliminate interventions targeting hotspots, migrant and mobile workers
- Support research and development of new antimalarial drugs
- Develop partnerships with industry, multilateral and financing bodies, including donors, and across all sectors of government.

5. The Australian government should consider new forms of private sector partnerships in PNG. These include partners with a strong community presence associated with mining, resources, and forestry industries, as well as with communities, local authorities and the PNG government to support the implementation of local malaria control and elimination strategies. By assisting the creation of innovative, multi-sectoral partnerships harnessing the private sector to help PNG achieve malaria control and subsequent elimination, this initiative will provide a solid foundation towards achieving these gains at a time when traditional global funding sources are stretched.

## **Background**

### **Medicines for Malaria Venture (MMV)**

MMV is an international non-profit foundation established in 1999 to discover, develop and deliver new, affordable antimalarial drugs<sup>3</sup> through effective public-private partnerships. MMV is a global, multi-stakeholder public-private and civil society collaboration that mobilizes and shares knowledge and expertise, technology and financial resources to address the global health challenge posed by malaria. Partners include the WHO, Global Fund to Fight AIDS, TB and Malaria, academia, industry, NGOs, International Organizations, National Malaria Control Programmes and the private sector, including Australian resources companies. MMV

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<sup>2</sup> Hewitt, S. Palmer, K. Ensuring Access to Medicines for High-Risk Populations March 2014 available at [www.aplma.org](http://www.aplma.org)

<sup>3</sup> Thirty-five countries are responsible for 98% of the total malaria deaths worldwide including 5 countries in the Asia-Pacific region: India, Myanmar, Bangladesh, Indonesia, and Papua New Guinea (PNG). In addition to loss of life, malaria has a significant impact on development - around 10 million school days are lost per year from malaria and its economic impact is estimated at \$12 billion per annum. Over the last 5 years, a number of interventions in malaria-endemic countries have achieved some important reductions in morbidity and mortality. However, progress is now threatened by the emergence of parasite strains resistant to the ACTs in areas of South East Asia (Cambodia, Myanmar, Thailand and Vietnam), as well as to primaquine in PNG.

is funded by Foundations (BMGF, the Wellcome Trust, ExxonMobil Foundation), Governments (including the US, UK, Norwegian, Swiss, Japanese, Irish and Australian) and the private sector.<sup>4</sup>

MMV is recognized as the leading product development partnership (PDP) in the field of antimalarial drug research and development (R&D). Over the period 1999-2013, the organization and its partners have brought forward four new antimalarial drugs (Coartem® Dispersible, Eurartesim®, Pyramax®, Artesun®) and assembled the largest pipeline of antimalarial drugs in history. MMV is currently involved in more than 60 R&D projects from discovery to late-stage development. It is a pioneer of the virtual pipeline model, managing R&D partnerships with over 375 global partners.<sup>5</sup>

The Australian government has provided valuable support to Medicines for Malaria Venture, recently announcing a \$10million, three-year commitment to support malaria drug development. This funding will be invaluable in the development of new, low cost medicines to protect against drug resistance.

### **Papua New Guinea and malaria**

PNG is one of only three malaria-endemic countries within the Pacific Region and bears about 98% of the malaria burden in the Pacific. There were 46 malaria deaths per 100,000 in 2010 compared with 24 in the Solomon Islands.

The population of PNG currently has a life expectancy at birth of 62.42 years, and mean school attendance of approximately 4 years, ranking 157 of a total of 187 countries listed in the UN Human Development Index. Despite 14 consecutive years of economic growth, there has been little change in poverty levels, and the level of inequality has increased. There is no certainty that economic growth will deliver sustained improvements in health and wellbeing for the majority of the population, which raises ongoing questions about the capacity of PNG to strengthen its health system and malaria control (and elimination) efforts.

The PNG National Department of Health (NDoH) National Malaria Control Strategic Plan 2014-2018 is focused on achieving and sustaining universal coverage and access to malaria control interventions. The goal is to achieve a substantial and sustained reduction in the malaria burden in PNG. The seven main objectives supporting this goal are as follows: (1) maintain high coverage of long-lasting insecticide-treated bednets (LLINs) and increase the utilisation of appropriate malaria prevention measures, (2) maximise access to and utilisation of early diagnosis and appropriate treatment for malaria (EDAT), (3) Strengthen malaria epidemic preparedness and response capacities at all levels, (4) maintain malaria monitoring and evaluation (M&E) systems and continue to develop the national capacity for surveillance, (5) Expand Public Private Partnerships (PPPs) for key malaria interventions, (6) Strengthen malaria advocacy, communication and social mobilisation (ACSM), (7) Further strengthen malaria program management at all levels with district levels as the priority.

The funding to enable the implementation of this Plan has been under significant review for some months between the PNG Government, NDoH Malaria National Technical Working Group and the Global Fund. The original funding sought to implement the plan has not been fully obtained and the Global Fund signed the agreed funding contribution to PNG in early February 2015. Further discussions are underway to seek additional funding to enable the continued PNG-wide distribution of LLINs.

Weak regulatory capacity and ineffective delivery channels, the potential threat posed by drug resistant parasites, the diverse spread of PNG's population, the lack of an effective health system are all challenges to malaria control in PNG. For example, a recent ANU study highlighted the lack of progress made by PNG's health clinics, which have been "starved of resources," with 41 per cent not receiving external support in

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<sup>4</sup> MMV currently supports Australian R&D institutions to the sum of USD 2-3 million per year, with additional funding being directed into the Asia-Pacific region, which is of key strategic interest to Australia [1]. In 2013, MMV received support from the Australian Government by way of a grant from AusAID (AUD 2.5 million).

<sup>5</sup> 28 pharmaceutical companies, 13 biotech companies, 56 universities, 38 research institutes, 72 clinical sites, 260 service providers, 50 government agencies.

2012.<sup>6</sup> Health workers are available at government clinics only 60% of the time, compared with 83% of the time at church-run clinics, and 20% of users rate the government run clinics as “poor.”

The United Nations Millennium Development Goals Gap Task Force Report (2014) noted that to improve access to medicines, treatments must be available and sufficiently affordable to patients. Prices of generic medicines remain high for patients in low- and lower-middle income countries, and average three times higher than international reference prices.<sup>7</sup>

Against this background, The United National Development Program (UNDP) notes that “Papua New Guinea is witnessing a ‘paradox of plenty’, where the country’s resource wealth is not translating into increased opportunities and capabilities for all Papua New Guineans, especially the large majority in the rural areas, and particularly vulnerable and marginalized segments of society.”<sup>8</sup>

Furthermore, overcoming vulnerability to infection and disease extends beyond health, to include transportation, public works, education, labour mobility, employment, social and cultural factors. PNG, as a near neighbour with unacceptably high malaria rates will require national, regional, and global support to build the capacity to meet the malaria challenge.

## Policy Context

### Australian Aid Policy, health and malaria

The Australian government has adopted an “aid for trade” policy linking overseas assistance to measures to promote economic diplomacy and growth across the region. This policy highlights the role of industry and mutual economic benefit. Within this context Dr Mark Dybul, head of the Global Fund to Fight AIDS, TB and Malaria notes “you don’t get economic growth if you don’t have healthy, educated people.”<sup>9</sup> The private sector has pushed for a healthier, better educated population to build a productive workforce, and a healthy, educated population that forms a market for products.

The path to a malaria-free Asia Pacific by 2030 will require distinct phases ranging from controlling transmission and impact of malaria, through to halting the spread of disease and preventing its reintroduction. Building mechanisms to provide a framework for regional co-operation, reviewing past experiences, and working together towards agreed goals, will help to identify how to scale-up innovative approaches to development cooperation. Strengthening partnerships, including political and financial support with member States and other development agencies, are essential preconditions for success. Similarly, as acknowledged at the conference Malaria 2012: Saving lives in the Asia Pacific, containing the spread of drug resistant forms of malaria will require complementary strategies in areas such as regional trade in counterfeit or low quality medicines, migration, deforestation and climate change.

The Australian government has “a policy of Australian aid for health, particularly health systems, to enable women, men and children to achieve better health, and live healthy and productive lives, particularly in Asia and the Pacific. Australia invests particularly in health systems, seen as an investment in economic prosperity, poverty reduction and financial protection.”<sup>10</sup>

Australian aid for malaria, including to PNG, may benefit from greater policy clarity particularly in relation to broader regional approaches to malaria elimination.

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<sup>6</sup> Stephen Howes, Andrew Anton Mako, Anthony Swan, Grant Walton, Thomas Webster and Colin Wiltshire October 2014 A Lost decade? Service delivery and reform in PNG 2002 - 2012

<sup>7</sup> <http://www.un.org/en/development/desa/news/policy/mdg-gap-report2014.html>

<sup>8</sup> 2014 National Human Development Report Papua New Guinea, available at [www.hdr.undp.org](http://www.hdr.undp.org)

<sup>9</sup> Development Policy blog: The future of the Global Fund [www.devpolicy.org](http://www.devpolicy.org)

<sup>10</sup> <http://aid.dfat.gov.au/aidissues/health/pages/home.aspx>

## **WHO Global Malaria Action Plan and related multi-lateral programs**

The Global Malaria Action Plan, promoted by the World Bank aims to permanently reduce malaria mortality and morbidity by scaling up health systems and delivery capabilities to sustain control and eventual malaria elimination. GMAP notes that countries need a tailored approach to control malaria, with tools appropriate for various settings. Epidemiological and logistical factors will determine the package of interventions to be implemented in each district. These include the more specific use of habitats by the main malaria vector species, and logistical factors which will affect the delivery of the proposed malaria control programs. These include variables such as population, transport, infrastructure, communications, and state of local health systems. These are country-level decisions, informed by WHO recommendations. Control measures include seasonal and environment controls, along with distribution of bed nets. Multi-stakeholder partnerships that mobilize and share knowledge and expertise, technology and financial resources will be required to end deaths from malaria.<sup>11</sup>

### **East Asia Summit, 2014**

On 14 November 2014, the leaders of the 18 East Asia Summit countries committed to an ambitious goal of a malaria-free Asia Pacific region in the next 15 years. This commitment will be replicated in the new Global Malaria Technical Strategy and Global Malaria Action Plan to be released in 2015 for the World Health Assembly ratification.

While neither PNG nor the other two malaria-endemic Pacific nations, Solomon Islands and Vanuatu, are member countries, the Summit's malaria-free objective has important implications given the cross border transmission of malaria and the projected pathway of drug resistance from Cambodia, Myanmar and Thailand.

### **Asia Pacific Leaders Malaria Alliance (APLMA)**

Regional governments have recognised that the responsibility for malaria elimination does not reside with any single country alone, some of which do not have the resources to address the regional and global threat posed by growing drug resistance. Governments share the responsibility across the region and beyond.

The Australian government has provided strong regional leadership through the APLMA. Established in 2013, this Alliance aims to provide the high-level leadership necessary to reduce malaria cases and deaths by 75% by 2015. It is recognised that eliminating malaria demands action across a broad front, extending beyond health services. It will require strong political commitment. Governments, (including PNG), need to prioritize the disease, co-ordinate their responses across borders, implement effective programme management and commit sufficient levels of finance. It will be important to consider PNG in the context of the APLMA program to ensure regional policy and program co-ordination and consistency.

### **Asian Development Bank**

The Asian Development Bank has established the Regional Malaria and Other Communicable Disease Threats Trust Fund, which is one of the tools available to support regional cooperation to tackle malaria. The Australian government has committed \$18 million to this Fund.

### **APMEN**

The Asia Pacific Malaria Elimination Network is a network of partner governments, donor organisations and public health, academic and private sector institutions in Asia and the Pacific. APMEN aims to develop and sustain a network of partner countries and institutions to work collaboratively to address the challenges of malaria elimination, with particular focus on the unique challenges for the region such as *Plasmodium vivax*. APMEN seeks to achieve this through activities relating to leadership, advocacy, capacity building, knowledge

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<sup>11</sup> United Nations Development Group, 25 September 2014

exchange and building the evidence base. PNG is not currently a member of APMEN, but is surrounded by APMEN member countries, each of which have made specific and time-bound, public commitments for achieving sub-national to national malaria elimination. However work has been undertaken through successive MMV Consultants to interface with PNG's NDoH and the National Malaria Technical Working Group to advocate for PNG membership in APMEN. PNG is essentially the only non-APMEN member within Asia Pacific. This advocacy campaign successfully culminated in the Feb. 2015 decision by NDoH's Senior Executive Management Team to promptly proceed with its APMEN application. The underlying logic supporting the application is provided by two malaria elimination projects initiated by MMV and its partners, namely the Lihir Group Malaria Elimination Project and the Manus Province Pilot Malaria Elimination Project.

### **MMV and Australian Aid**

In 2013-2014 the previous Australian government announced a \$10million program support Product Development Partnerships, including \$2.5 million to support MMV's portfolio of drug development. MMV applauded the Australian government for taking this first step towards supporting MMV's drug development portfolio in accordance with MMV determined priorities.<sup>12</sup> In March 2015 the Minister for Foreign Affairs and Trade announced a further \$10 million over three years, so accelerating the government's support for malaria. This funding demonstrates a valuable commitment to ensuring the development of tools and technologies for malaria, and complements regional strategies to build systems to eliminate malaria.

### **The Scope for Expanding Private Sector Partnerships**

The 2014 National Human Development Report, compiled by the UN Development Program noted "Papua New Guinea (PNG) stands at a critical moment in its development. With Gross Domestic Product (GDP) growth over 20 per cent expected for 2015, following the start of production from the massive PNG Liquefied Natural Gas (LNG) project, the country has a unique opportunity to leverage significant sustainable and equitable improvements in levels of health, education, income and other elements of inclusive human development... If poor choices are made, the impact of the high growth rates will be limited, even detrimental..."<sup>13</sup>

The non-government sector is increasingly active in international development cooperation. This includes both the philanthropic and industry sectors, which, offer the potential to make a bigger contribution to eliminate poverty and support economic growth, and to deliver 'global public goods.'

Product Development Partnerships such as MMV, FiND and the TB Alliance, combining resources and technical expertise through a process of international coordination offer a proven model of public/private/philanthropic co-operation beyond that which can be generated by a single agency or country. The development of new technologies, including diagnostics and medicines cannot be achieved without this pooling of funding, expertise and capabilities.

Non-government organizations, such as MMV, working with industry partners, can work locally to test and introduce innovative approaches to promote health, consistent with sustainable development principles.

### **Case Study: MMV Resources Industry Partnerships in Papua New Guinea**

MMV has recently helped to develop the following partnerships in PNG focused on malaria operational research and implementation projects, with major Australian and PNG resource sector companies. Private sector partnerships have demonstrated their capacity to be a catalyst to establish the foundations for future programs that bring together a broad range of stakeholders, including governments and donors.

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<sup>12</sup> The 2014-2015 Federal budget included a \$30 million per year allocation for global health and medical research. Subsequent cuts to foreign aid, announced in late 2014 have raised serious concerns about the government's commitment to providing the full amount of funding under this program.

<sup>13</sup> 2014 National Human Development Report Papua New Guinea, available at [www.hdr.undp.org](http://www.hdr.undp.org)

- **Newcrest – MMV Malaria Alliance:** This initial 5-year alliance created in 2011 covers malaria control, prevention and case management across Newcrest's global gold mining operations in PNG, Indonesia and Cote d'Ivoire. The Alliance has now moved to implement the recommendations of a malaria elimination feasibility study by IS Global (2014, University of Barcelona) covering the Lihir Group of islands in New Ireland Province, PNG, which hosts Newcrest's world-class Lihir gold operation. This includes securing the engagement and commitment of local partners and engagement with key stakeholders; program design and development of governance arrangements. This project will be the first private sector malaria elimination project in PNG and would provide an important pathway for other comparable potential private sector projects conducted through the PNG Industry Malaria Initiative (PIMI: See below).
- **Oil Search Health Foundation (OSHF) – MMV Alliance:** The Alliance has recently completed a 2-year project focused on OSHF's Medicine Store Keeper (MSK) model (a social franchise model focused on providing affordable malaria diagnosis and treatment through private shops). The model was piloted in the Southern Highlands of PNG, and MMV has worked closely with OSHF to develop a business implementation plan to permit expansion of the model to other parts of PNG.
- **PNG Industry Malaria Initiative (PIMI):** In mid-2013 MMV, with support from OSHF, initiated a Public-Private Partnership (PPP) with the resources sector, named the PNG Industry Malaria Initiative (PIMI). The objective of the initiative is to mobilise PNG's world class agribusiness, energy and mining operations to support implementation of PNG's National Malaria Control Strategy by entering PPP's with their host provinces with the aim of achieving PNG-wide malaria elimination.
- **Bougainville accelerated malaria control proposal:** In late 2013 MMV supported an accelerated malaria control project for Bougainville. This project has been supported by DFAT and there has been strong support for the scoping study phase of this project by the Autonomous Government of Bougainville, Bougainville Copper Limited and the PNG Department of Health. On-going commitment will be critical to success.
- **Manus Province malaria elimination pilot project proposal:** In late 2013 MMV proposed a pilot malaria elimination project for Manus Province. Strong support for the scoping study phase of this project was obtained from a broad range of key provincial and national political and civil stakeholders. World Vision Australia agreed to fund the initial scoping study phase which started in January 2014 and completed in August 2014. The project commenced feasibility studies under the guidance of the Manus Province Malaria Alliance (MPMA) Steering Committee in October 2014. Transfield Services, the Lombrum Detention Centre facilities manager, is currently providing part funding with additional funds anticipated from both the Manus Provincial Government and DFAT PNG. Discussions are in progress with the Department of Immigration and Border Protection (DIBP) for their potential involvement completing an aligned study over Lorengau Township due to it hosting the Lorengau East Detention Centre. The PPP model being developed in Manus by the MPMA project is seeking to build on the potential community outreach impact of the various parties involved in the Lombrum and Lorengau East Detention Centres. The current funding strategy is designed to advance the project through definitive feasibility study without approaching any major international donor (beyond DFAT) who would be essential to partner with the PNG and Manus Provincial Governments for implementation funding.

#### **Projects under development leveraging against the momentum gained in Manus and Bougainville**

- **New Ireland Province Malaria Alliance:** A proposal to develop a New Ireland provincial scale alliance including five industry operators (Newcrest, St. Barbara, Nautilus Minerals, New Britain Palm Oil Limited and Anitua), the provincial government, NDoH and at least one NGO (Australian Doctors International).
- **Economic Cost of Malaria to PNG Project:** MMV has initiated a research project for the PNG Institute of Medical Research designed to use the economic model developed by Accenture ("The Economic Case for Combating Malaria") published in the American Journal of Tropical Medicine and Hygiene (89-5, 2013, pp. 819–823) in the context of Papua New Guinea ("PNG"). The final report is currently being drafted.

- **Proposed Asia/Pacific Study Tour:** to observe and gather information on the key components of the pre-feasibility (PFS) and definitive feasibility studies (DFS) work undertaken in these countries, including valuable lessons learnt. The NDoH's SEM has requested that both an NDoH malaria officer and a Manus Province Provincial Health Authority officer be included in the Study Tour participants.

These initiatives show that international development for poverty alleviation and international development for national, political and economic aims need not be mutually exclusive. Instead, what is needed is a holistic approach that uses the funding, reach, technical know-how, dynamism and political power of government, not-for-profits and industry to craft and implement solutions for the benefit of malaria-endemic communities.

The success of organisations such as MMV highlights opportunities to further support Product Development Partnerships to address global health issues that would otherwise be beyond reach. MMV's impact on saving lives by the distribution and use of their co-developed antimalarials, particularly in Sub-Saharan Africa, and programs in the Mekong Delta and Australia's near neighbours, provide a demonstration of the value to governments, of working with multilateral development organisations.

### Summary of Specific Challenges

MMV has successfully catalyzed and coordinated action by a diverse range of international partners, including the private sector, governmental agencies, local malaria control programs and research institutions. The challenge is to adapt and apply new innovations, tools and technologies within the context of countries such as PNG.

PNG confronts a range of development challenges, and the path to achieving malaria control and elimination will require support and assistance well into the future. Specific challenges that will be critical in the development of Australian aid to PNG include:

1. The development of government, institutional and economic mechanisms that can better connect resource wealth with social development.
2. Belated global recognition of the need to effectively confront *Plasmodium vivax* present in PNG and related requirement for specific drug and diagnostic development
3. Existence of emerging artemisinin resistant and multi-drug resistant *Plasmodium falciparum* parasites within the Greater Mekong Sub-Region, potential for regional spread, and the related threat to the entire class of current first-line artemisinin-based combination therapy drugs
4. Concern about a spread into Asia and the Pacific of insecticide resistance by the *Anopheline* vectors. A loss of effective chemotherapy and insecticides will have major implications for deadly resurgence of malaria into the region, especially amongst children under 5 and pregnant women – and cause reversal of gains made in MDGs 4, 5 and 6.
5. In 2014 the Global Fund announced significant cuts to funding for malaria control in PNG, requiring domestic governments to step up their national malaria funding commitments.
6. The shared borders with Indonesia and the Solomon Islands offer additional malaria control and elimination challenges due to cross border transmission.
7. Limited financial commitment from the PNG government, limited community access to treatments, poorly developed health system and capacity constraints.
8. The need to strengthen drug regulation and protection against the use of poor quality drugs and monotherapies.

[Appendix: Reddy D, Spigelman M \(2014\) Product Development Partnerships: an innovative approach to tackling neglected diseases](#)

[www.mmv.org](http://www.mmv.org)



## Appendix:

### Product Development Partnerships: an innovative approach to tackling neglected diseases

By David Reddy and Mel Spigelman on May 28, 2014



Product Development Partnerships (PDPs) have been active, and actively engaging Australian research expertise, for over ten years. Only now is their significant contribution to global health being fully recognized. PDPs offer a new way of meeting development aims consistent with the government's interest in increasing engagement with the private sector to achieve better development outcomes, as well as raising productivity and private-sector-led economic development. Australian scientists have made a significant contribution from the earliest beginnings of this innovative global approach to tackling diseases such as TB and malaria.

PDPs are public-private partnerships that reduce industry and donor risks for investment in neglected disease research by leveraging funding and employing strict portfolio management strategies. Partner funding is pooled to support broad product pipelines, allowing partners, including governments and private sector players, to contribute to the R&D enterprise without having to bear the entire cost and risk themselves. Strong governance structures ensure programs are conducted efficiently, and include independent review of projects as they progress through defined transition points.

Today there are 16 major PDPs operating globally, each with a specialized focus on vaccines, microbicides, preventative treatments, therapeutic products or diagnostics. PDPs have developed a unique model with the following characteristics.

- Missions to develop and deliver affordable, quality medicines, vaccines, diagnostic tools and innovative products for specific neglected diseases to combat poverty and disadvantage.
- A focus on developing products that would be unlikely to be developed through normal commercial channels owing to market failures, and providing funding and expertise to translate basic science and early discovery work into products that save lives.
- Diversified product portfolios – MMV and TB Alliance jointly have more than 60 products under

development and four drugs registered and being distributed globally, with the support of the Global Fund to Fight AIDS, TB and Malaria.

- A commercially-oriented lean operating model – TB Alliance and MMV each operate with staff of less than 60, with all laboratory work and clinical trials contracted out and administrative costs kept to a bare minimum. Regular expert reviews of progress inform decisions on which projects to terminate and which to progress into increasingly demanding (and expensive) clinical trials, with the ultimate objective being registration for use in relevant markets.
- Private sector partners that assign intellectual property rights back to PDPs in relation to the intended use of a product under development, often by means of a royalty-free license or preferential, affordable product pricing in developing country markets.
- Multiple donor partners, including foundations (such as the Bill and Melinda Gates Foundation, the Wellcome Trust and the Rockefeller Foundation), governments (such as the UK, US and Ireland) and industry partners.
- Substantial in-kind contributions from industry and research partners – MMV and the TB Alliance recently estimated the value of the in-kind contributions they receive to be around 0.6 to 1.5 times the value of cash contributions from donors, and a number of R&D partners also provide co-funding for projects.
- A global partnership network free of national, regional or local or industry politics that includes funders, industry, academia, United Nations funds, programs and organizations, ministries of health, civil society, affected populations, and contract R&D organizations.
- A centralized, product-focused, expert knowledge hub that executes its work through partnership networks that reach across national boundaries and multiple jurisdictions, from the World Health Organization to remote communities in impoverished nations – MMV alone works with 300 partner organizations, including 67 in Africa and 70 in Asia and Oceania.

The work of PDPs is becoming increasingly relevant as Australia strengthens its ties with the Asia-Pacific region. More than one billion people in Asia are infected with TB, and the direct and indirect economic cost of TB has been estimated at \$23 billion a year in [India alone](#). The 22 countries of the Asia-Pacific are also home to approximately 67 per cent of the world's population at risk of malaria – some 2.3 billion people – and Southeast Asia is the global epicentre for drug-resistant forms of the disease.

For over a decade Australian scientists have partnered internationally through PDPs but, despite their strong track record globally, the contribution of these mechanisms is not widely recognized locally. It was, however, recognized by the 2011 Independent Review of Aid Effectiveness which recommended 'more aid funding for research by Australian and international institutions, particularly in ... medicine' (Recommendation 23). At that time, AusAID was something of an exception among leading international government aid agencies in that it did not invest in health product development at all, and had only a piecemeal operational health research strategy.

Responding to the above recommendations in 2012, the previous Australian government allocated a total of \$40 million over five years for health research and development, including \$10 million in funding for four PDPs, under the AusAID Medical Research Strategy. This was a significant breakthrough, signaling Australia's commitment to advancing innovative global health product development. PDPs welcomed the emergence of opportunities to form enduring, co-operative partnerships with Australian research centres. Following the change of government in September 2013, ongoing funding is in serious doubt, complicated by changes in aid allocation and administration, and the absence of an overall policy framework for Australian aid.

The Abbott Coalition government has expressed a strong commitment to the provision of development assistance to the Asia-Pacific, where malaria and TB are endemic. While it has not explicitly endorsed the previous government's commitment of \$40 million to health research and development, the work of the PDPs funded to date is clearly aligned with the Coalition government's regional health and economic objectives and its stated private sector engagement objective.

The Coalition government has of course laid heavy stress on increasing the results orientation of the Australian aid program. That comes as good news for PDPs. The results of PDP funding to date were highlighted by two major PDPs, the Global Alliance for TB Drug Development (TB Alliance) and the Medicines for Malaria Venture (MMV), in their submission to the Senate Foreign Affairs, Defence and Trade Committee Inquiry into Australia's Overseas Aid and Development Assistance Program:

With critical funding from the Australian government this past year and with the leveraged expertise of Australian partners – including Griffith University, Monash University, and the Queensland Institute of Medical Research (QIMR) among many others – our organizations are poised to deliver multiple improved health products to market for TB and malaria within the next 2 years. Products advanced to late stage development with support from the Australian Government will dramatically reduce health system costs and improve millions of lives, reflecting tremendous value for money. A [recent study](#) projected a net economic output of US \$208.6 billion from 2013-2035 as a result of malaria reduction and elimination interventions. Likewise, new tools in development for the treatment of multi-drug resistant forms of TB are expected to reduce treatment delivery costs for some forms of MDR-TB by over 90%. In a current context in which treatments for extensively drug-resistant TB (XDR-TB) can cost health systems up to \$1 million per patient to deliver – as recent cases in Queensland evidenced – investment in innovative treatment tools represents an incredibly cost effective intervention.

A new TB test, developed through a PDP, has cut the diagnosis time for drug-resistant TB from nearly two months to as little as two hours (very important when the average Multi-Drug-Resistant TB (MDR-TB) patient infects one or two other people each month, at a large cost to health systems and aid donors). Further, new TB regimens entering Phase 2 testing could allow a two-to-three month treatment course instead of six months (for drug-sensitive TB) or two years (for MDR-TB), generating enormous health systems cost-savings in countries like PNG and also in countries like Australia that currently share such costs.

Encouragingly, the report of the Senate Foreign Affairs, Defence and Trade Committee inquiry, which was release on 27 March, 2014, strongly supported an expansion of Australia's contribution to global health, recommending the Australian Government renew the Medical Research Strategy and expand funding for it to \$50 million per annum. The Committee strongly supported research and development through PDPs, noting that Australia's initial 2013 investment of \$10 million in four PDPs 'has delivered a high return on investment, supporting a portfolio of 71 drug, 14 vaccine and 19 diagnostic projects.'

Few would disagree that building a healthier community is critical to building productive workforces and a strong, stable global economy. The challenge remains for PDPs, Australian science, governments and policy makers to find ways to do business together, in a way that accelerates the



pathway toward effective disease control and elimination, and resolves the barriers that currently get in the way of doing business together. PDPs are ‘open for business.’

*David Reddy is CEO of the [Medicines for Malaria Venture](#). Mel Spigelman is President and CEO of the [TB Alliance](#).*