Product Development Partnerships
Submission: Australia's International Development Policy
November 2022

Global health – a key priority for international development

This submission is drafted by four world-leading product development partnerships (PDPs) working in global health. We receive funding through the Indo Pacific Centre for Health Security at DFAT.

We call on the Australian government to **prioritise global health research and development (R&D) in its new development policy and maintain its commitment to tackling infectious diseases in the Indo-Pacific – diseases that are intertwined with regional security and prosperity**.

Undermining progress towards the UN SDGs and pushing millions of people back into poverty, the COVID-19 pandemic has reinforced the need for global cooperation to provide equitable access to health services and medical countermeasures (diagnostics, treatments, vaccines etc) and to address the inadequacy of health systems.

Australia has played a leadership role in tackling the COVID-19 pandemic in the Indo-Pacific region through multilateral and bilateral programs delivering vaccines and treatments as well as strengthening health systems. This focus builds on Australia's 2017 Foreign Policy White Paper which acknowledged three key principles which were prescient and continue to be critical:

1. Health crises threaten economic and human development
2. International travel, urbanisation and weak health systems in some countries contribute to the rapid spread of pathogens around the globe
3. Antimicrobial (AMR) and insecticide resistance are major threats to global health. If not tackled decisively, AMR could cause an additional 10 million deaths per year; similarly, failure to mitigate and manage insecticide resistance is likely to result in an increased burden of disease.

The pandemic threat will remain a challenge for Australia and the world in the foreseeable future and will need to be addressed by bilateral means as well as multilateral mechanisms such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the newly established Pandemic Fund for prevention, preparedness and response, hosted by the World Bank.

The pandemic has disrupted health services globally and derailed progress towards achieving SDG3 to end HIV, tuberculosis (TB) and malaria and other diseases of poverty, particularly in the Indo-Pacific region:

- A 2020 report by the Global Fund to Fight AIDS, Tuberculosis and Malaria shows that malaria diagnoses fell 56% and malaria treatment services by 59% in Bangladesh, Cambodia, India, Indonesia, Laos, Pakistan and the Philippines. The greatest disruption was reported in rural areas where the more vulnerable and harder-to-reach communities live. According to the Asia Pacific Leaders Malaria Alliance (APLMA), the region faces the biggest malaria burden (90%) in just five countries - *India, Papua New Guinea, Indonesia, Pakistan and Afghanistan* – and the poor and marginalised face the greatest risk of exposure. In Papua New Guinea, COVID-19 threatens to radically disrupt malaria prevention and treatment services.
- An estimated 10.6 million people globally fell ill with tuberculosis (TB) in 2021, an increase of 4.5% from 2020, and 1.6 million people died from TB (including 187 000 who were HIV positive), according to the World Health Organization's 2022 Global TB report. The burden of drug-resistant TB (DR-TB) also increased by 3% between 2020 and 2021. Similarly TB referrals fell by 59% in 2020 relative to 2019. Two-thirds of the total global tuberculosis burden – more concerning, the multi-drug-resistant variant of TB – is in the Asia Pacific region.

As well as continuing to invest in vaccines, therapeutics, vector control, diagnostics and health systems, it is vital that the Australian Government continues to invest in the research and innovation needed to drive breakthroughs in life-saving technologies and respond to the changing burden of disease including, pandemics, communicable diseases and antimicrobial resistance.

We call on the Australian Government **to continue to invest in product development partnerships (PDPs)** and thus support the accelerated development of a range of new tools that can respond quickly to current and emerging threats. The persistence of poverty-related diseases shows that millions of people suffer because market-based incentives are insufficient to develop an arsenal of essential medical technologies. PDPs represent a different and effective approach, leveraging donor investment and multi-sectoral partnerships to develop solutions for pressing health crises while ensuring equitable access and value for money.

The role of PDPs in global health

PDPs are international, not-for-profit organisations that create transformative health innovations. They develop vaccines, drugs, vector control products and diagnostics for neglected and poverty-related diseases, which disproportionately affect disadvantaged and marginalised people living in low- and middle-income countries. PDPs also advance access to these medicines by working with partners to promote regulatory harmonisation to accelerate the global availability of co-developed products.

Free from the profit motive, PDPs fill an important gap in the global health innovation pipeline. Typically, they have a strong international network of collaborators from public and private sectors – scientists, clinicians, industry partners, government agencies and non-governmental organisations – which they can draw upon to address global health challenges. As such, they bring a ready-made package of international expertise to bear on the health security agenda.

By building on its current investment in PDPs, the DFAT can leverage additional funding from the Bill & Melinda Gates Foundation (BMGF), the UK Foreign Commonwealth & Development Office (FCDO) other international aid organisations and industry partners. In the case of malaria, the investment impact is even higher: every dollar invested raises an additional USD 2.50 thanks to direct and in-

kind support from partners. Recently approved drug-resistant TB treatments, developed with DFAT investments, can save national governments up to US$740 million annually. These savings could allow 400,000 more TB patients to be treated.

Global Health challenges from climate change

It is widely acknowledged that **climate change** is a threat to the livelihoods, security and well-being of the peoples of the Indo-Pacific and needs to be factored into health systems planning.

According to The Lancet Countdown on Climate Change and Health, global health systems weakened by the COVID-19 pandemic are increasingly affected by extreme weather events. The changing climate is affecting the spread of infectious diseases as warmer coastal waters become more suitable for the transmission of pathogens. For example:

- Between 2015 and 2019, climate suitability for the transmission of malaria increased by ~39% and ~150% for regions in Africa and the Western Pacific, respectively.
- From 1950 to 2018, the global climate suitability for the transmission of dengue fever increased by 8.9% for *Aedes aegypti* and 15.0% for *Aedes albopictus*. These mosquitoes are also the principal vectors for chikungunya, dengue, yellow fever and Zika virus.

Though an evolving field of research, evidence suggests that the rise in extreme climatic events is likely to affect the susceptibility of individuals to TB by increasing the prevalence of its underlying risk factors, particularly in developing countries. These climatic events could create a conducive environment for TB transmission and disrupt TB diagnosis and treatment services.

Health Equity

We support the Government's commitment to stated gender objectives, as well as to strengthening equity and diversity policies as well as social inclusion.

Women and girls are uniquely affected by the health, economic and societal impact of neglected diseases. Sex and gender play an often underestimated and ill-understood role throughout the R&D and implementation process for all health technologies.

For diagnostics and testing, gender norms and roles are critical determining factors to ensure the first step – diagnosis – is not missed in the cascade of care. Everyone, regardless of gender, will need a diagnostic test at some time in their lives, yet gender roles can exacerbate specific access barriers. In healthcare delivery, women themselves have a crucial role to play. Universal Health Coverage, including essential diagnostic testing, will primarily be delivered by women, as they form the vast majority of the health and social care workforce.

The Government should consider expanding investment into R&D that addresses gender inequity in health innovation to enhance community resilience. Pregnant and lactating women have long been excluded from biomedical R&D, resulting in gaps in targeted medicines and relevant data. Global regulators and others have called for action in this area. In malaria-endemic regions, and this includes the Asia-Pacific, malaria in pregnancy is a serious public health problem requiring new, customised antimalarials. These targeted medicines will reduce maternal and child deaths, improve gender equality and help end malaria. MMV's MiMBa strategy aims to expedite the discovery, development, and delivery of antimalarials to treat and protect this population.

On the policy front, women political leaders have shown their formidable influence in prioritizing health issues. At the community level, women are important health influencers in families and communities.

Funding for Global Health

We suggest that Australian funding for global health programs, research and innovations be increased commensurate with other OECD countries, particularly for the world's most vulnerable populations.

The latest G-Finder report by Policy Cures Research shows that although funding for neglected diseases has remained relatively stable … 'there remains the risk of future fiscal contractions that may reduce governments' budgets'. This is on top of the decline in investments from multinational pharmaceutical companies for the second consecutive year from 2020.

Moreover, there is a paucity of global health research funding in Australia and we support the need to scale up investment in this area. The Indo Pacific Centre for Health Security provides funding for regulatory harmonisation and $75m over 5 years for research on new drugs and diagnostics through the four undersigned PDPs.

In addition, the Medical Research Future Fund (MRFF) has committed only $30m over 10 years to better understand global health issues, whereas a more innovative and results-driven approach could dovetail with regional and international initiatives.

Partnerships are critical

The need for international cooperation in global health is acute and partnerships are critical to success in the region, as they bring capability, technology and knowledge advantages that one nation or organisation would not acquire or develop on its own.

In global health, Australia has established productive partnerships with GAVI, the Global Fund, the WHO and most recently the Pandemic Fund, among others. Existing regional structures, such as APLMA, work with 22 governments (including Australia) in the Asia-Pacific that have committed to eliminating malaria in the region by 2030.

The four PDPs featured in this submission – FIND (the global alliance for diagnostics), IVCC (the Innovative Vector Control Consortium), MMV (Medicines for Malaria Venture) and TB Alliance – have strong existing networks in Australia and the broader Indo-Pacific region, such that any investment made by the Australian government indirectly contributes to domestic and regional academia and industry.

One partnership model, Partnership for Vivax Elimination (PAVE) focusses on eliminating *P. vivax* – a complex and persistent type of malaria endemic to the region that poses a risk to more than one-third of the world's population. PAVE is led by MMV and PATH and combines a new investment of USD 25 million from Unitaid with work under existing grants from the BMGF, the UK FCDO and MMV core funding. This approach ensures coordination of efforts around the world.

TB Alliance has worked with 30 partners in the region, including Australian academic institutions like the University of Queensland and University of Wollongong. Further, research by a team at New Zealand's University of Auckland has been critical in advancing next generation diarylquinolines (an established class of anti-TB drugs) to clinical stage development. TB Alliance, through the PDP model, has partnered with several research, hospital, and academic institutions in Malaysia and the

Philippines. Continued investments ensure the acceleration and the development of new and improved TB drugs by building local capacity to conduct research for TB and other healthcare priorities including COVID-19.

About Product Development Partnerships (PDPs)

FIND, the global alliance for diagnostics, plays a crucial role in the development of and access to effective diagnostic tools for both patient management and surveillance. With the help of the Australian government, FIND has registered nine game-changing tests for TB and malaria since 2013, seven of which are registered in the Indo-Pacific region. Despite these important developments, gaps remain in the early identification of clinical and sub-clinical cases, as well as in the detection of resistance. In the coming years, FIND will focus on supporting development and deployment of near patient tests (including self-tests) and multi-disease platforms with the aim of optimizing and strengthening lower levels of the health system and empowering patients. These tools supported through accompanying digital infrastructure will also focus on building stronger health systems and surveillance infrastructure to address global health threats including AMR.

The Innovative Vector Control Consortium (IVCC) is the only PDP in the world working in vector control. Established in 2005, IVCC facilitates the development of novel and improved insecticides and formulations to combat the rapidly growing problem of insecticide resistance. Currently operating under a DFAT grant issued in 2018, IVCC is developing a vector control toolbox to enable the eradication of malaria and other vector-borne diseases, by identifying impactful products that are on the market, or close to market, and which can be evaluated for efficacy, effectiveness and scalability in the region.

Medicines for Malaria Venture (MMV) was established in 1999, when the malaria drug pipeline was all but empty and existing front-line drugs were failing due to resistance. After two decades, MMV, with its extensive network of collaborators (150 active partners worldwide), has now completely refreshed and reloaded the antimalarial pipeline, making it the largest in history – _thanks, in part, to the ongoing support of DFAT since 2013. Today, MMV manages a burgeoning portfolio, including 13 launched products. True to its original mission, it remains dedicated to providing under-served and at-risk populations with access to life-saving antimalarial drugs.

TB Alliance, established in 2000, is a PDP dedicated to the discovery, development and delivery of better, faster acting and affordable TB drugs. Through the support of DFAT, TB Alliance is transforming the treatment landscape by creating a new treatment paradigm for TB. Novel regimens such as BPaL hold the potential to address the full spectrum of treatment needs for TB. Current DFAT funding through the Regional Health Security Partnership Fund is catalysing Australia's efforts in research and innovation for an effective global health response to the TB pandemic.

For further information, please contact:
Leanne Joyce
Adviser, External Affairs
EM: joycel-consultants@mmv.org
MB: 0424 159 562