



Foreign Affairs, Defence and Trade Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

7 February 2014

Submission to the inquiry into Australia's overseas aid and development assistance program

Summary of key points

The current changes to the Australian aid program provide an opportunity to strengthen Australia's focus on the following strategic priorities:

- **Combating tuberculosis (TB) should be a clear priority of the aid program.**
TB is the infectious disease that causes the most sickness and deaths in the Asia-Pacific region and constrains economic growth. Drug-resistant strains require urgent responses and are creating complex new challenges. The aid program should increase measures to combat the infectious diseases that have the greatest health impacts in Asia-Pacific.
- **Medical research should be a flagship of the aid program**
The Government should fully implement the recommendations of the 2011 Independent Review of Aid Effectiveness, which called for the establishment of a medical research program as a 'flagship' of the Australian aid program. This requires funding of international research collaborations.
- **Public-private partnerships should be supported to develop new vaccines, diagnostics and drugs.**
Product Development Partnerships (PDPs) should continue to be funded from the aid program to enable use of public funds to leverage private sector resources to support medical research and development of new tools that have the potential to revolutionize the fight against diseases prevalent in developing countries.
- **The decision to discontinue funding support to the aid program's Medical Research Strategy should be reversed.**
Aeras welcomed the statement of the Foreign Minister Julie Bishop of January 18, 2014, confirming that priorities of the Australian aid program will include better health and leveraging private sector involvement to reduce poverty in the Indo-Pacific region. However, Aeras and other medical research agencies were deeply disappointed to receive advice from DFAT's Health Policy and Partnerships Section on January 20, 2014, that the Department is "*unable to continue to fund medical research at this time*" due to the cuts to the aid program budget for 2013-14.

The decision to discontinue medical research funding to Product Development Partnerships runs counter to the Government's stated priorities. This decision represents a serious setback to efforts to develop the new tools that are urgently required to fight TB and other priority diseases in the region.

As detailed below, the Australian aid program had only recently assumed a role in supporting international PDPs involved in medical research. Medical research conducted through public-private partnerships has the potential to improve health outcomes by leveraging private sector investments from pharmaceutical companies and biotechs. Sustaining support to medical research is crucial to enable Australia to meet its commitments to support global efforts to fight diseases of the developing world, particularly TB and malaria. For TB, Australia is committed to the Millennium Development Goal of reversing TB incidence by 2015 and the global goal of elimination of TB by 2050.¹

It is imperative that DFAT reestablishes support to the aid program's *Medical Research Strategy* and consolidates its role in medical research to address global health challenges. Continued funding of medical research under the aid program is also consistent with the Coalition's pre-election pledge to quarantine medical research from any funding cuts over the forward estimates.²

About Aeras

Aeras is a non-profit Product Development Partnership (PDP) dedicated to the development of effective tuberculosis (TB) vaccines that will be affordable, available and adopted worldwide. Aeras works in partnership with academic institutions and industry to develop a global pipeline of new TB vaccines suitable for use in developing countries. Aeras is one of four global PDPs that received support for medical research from the Australian aid program in 2013. The other PDPs receiving Australian aid program support were the Global Alliance for TB Drug Development, Medicines for Malaria Venture (MMV), and the Foundation for Innovative New Diagnostics (FIND). Aeras also receives support from the Bill and Melinda Gates Foundation, Government of the United Kingdom, Government of Netherlands and other European donors. Aeras is headquartered in the USA and has offices in China and South Africa.

A stronger focus on combating TB and other priority infectious diseases in Asia-Pacific

Economic prosperity in the Asia-Pacific region as a whole requires a strategic focus on combating the major infectious diseases that undermine workforce productivity in developing countries in Asia and the Pacific, particularly TB and malaria. Investment in health ensures healthy workforces in the region's emerging economies and reduces the financial burden to health budgets caused by diseases that are highly costly to treat, such as TB (including drug-resistant strains).

TB is the leading cause of death from infectious disease in Asia-Pacific. TB imposes significant costs on the health budgets and economies of our developing country neighbours. The economic impact of TB comes from the scale of the problem (with over 7.5 million cases in Asia-Pacific) and from the fact that in developing countries the majority of those affected are people in their most productive years.

¹ WHO (2006), *Global Plan to Stop TB*, Geneva: WHO.

² *The Coalition's Policy to Protect and Streamline Health and Medical Research Funding*, August 2013

Table 1 shows the number of TB cases in the eleven high-burden TB countries of the Asia-Pacific region. Four of these high burden countries (Afghanistan, Bangladesh, Indonesia and Pakistan) are not on track to reach one or more of the Millennium Development Goal (MDG) targets for reductions in TB incidence, prevalence and mortality.³ In addition to these high population countries, TB (including multi-drug resistant TB) is of increasing concern to Australia's near neighbours with high TB incidence including Papua New Guinea, Kiribati and Timor-Leste. PNG has the highest TB burden in the Pacific region with 15,000 new cases diagnosed each year.

Table 1: Prevalence of TB, Asia-Pacific High Burden Countries

Asia-Pacific High TB burden countries	Active TB cases 2012
India	2,800,000
China	1,400,000
Indonesia	730,000
Bangladesh	670,000
Pakistan	670,000
Philippines	450,000
Myanmar	260,000
Vietnam	200,000
Cambodia	110,000
Afghanistan	110,000
Thailand	110,000
AP Total	7,510,000
Global Total	11,908,057

Source: WHO, Global Tuberculosis Control Report 2013

The largest indirect cost of TB is lost income due to illness. Studies suggest that on average three to four months of work time are lost, resulting in average lost potential earnings of 20% to 30% of annual household income. For the families of those that die from the disease, there is the further loss of about 15 years of income because of premature death. When a woman suffers from TB, the household loses the benefits of the activities that women routinely perform, such as cooking, cleaning and childcare. The economic burden of TB between 2006 and 2015 for the twenty-two high-burden countries has been estimated be about \$3.4 trillion. China alone accounts for more than a third of the overall economic burden in these countries, and India and China together account for more than half.⁴

³ WHO (2013), *Countdown to 2015: Global Tuberculosis Report 2013 Supplement*. Geneva: WHO.

⁴ Laxminarayan R., Klein E., Darley S., and Ayedi O. (2009) Global investments in TB control: Economic benefits, *Health Affairs*, vol. 28 no. 4, w730-w742.

Improved treatment and prevention of TB will augment trade and economic growth in the region. This is recognized by industries that are central to Australia's economic interests, including the mining and energy resources industries. Several major Australian gold mining companies operate in Papua New Guinea, where TB is a leading cause of death and illness. TB has a direct impact on productivity of the workforce of mining companies such as Rio Tinto that operate in TB endemic countries, such as PNG, India and Indonesia. A recent sustainability report of BHP Billiton outlined the need to protect its workers against TB and other infectious diseases in high-burden countries where they have mines.⁵

The World Health Organization (WHO) estimates that \$8 billion is required per year for a comprehensive response to the TB epidemic between 2013 and 2015.⁶ Recognizing the limitations of existing tools to fight TB, WHO has defined the key components of a comprehensive response to comprise a dual strategy of delivering existing approaches while also supporting research into new vaccines and drugs. New vaccines and drugs are urgently needed to fight TB, particularly given the limitations of the current vaccine (which is ineffective to prevent TB in adults) and the emergence of drug-resistant TB strains.

Australia Aid should fund medical research to fulfill commitments to aid effectiveness

The Minister for Foreign Affairs has stated that the effectiveness of Australia's aid spend will be a "primary focus" of the new Government.⁷ Consistent with this focus, the Government should fully implement the recommendations of the Independent Review on Aid Effectiveness (2011). This included recommendations in relation to establishing a medical research program as a 'flagship' of the Australian aid program.

Until 2013, AusAID had no prior history of support to medical research to develop new drugs and vaccines for TB, malaria or other diseases prevalent in poor countries. The Australian aid program commenced support to medical research in 2013 in response to the recommendations of the 2011 Independent Review of Aid Effectiveness, which concluded that:

- The aid program should fund medical research by Australian and international institutions.⁸
- The aid program should prioritize funding research into vaccines for unmet medical needs of the poorest countries, with consideration given to research conducted by public-private partnerships such as Aeras and the Malaria Vaccine Initiative.⁹
- A new medical research program should be given special status as one of a small number of 'flagship' areas for the aid program. Flagships were proposed by the Independent Review that build on areas of Australia's comparative advantage, where Australia is well placed to add value in area of expertise to address neglected needs and issues on which a substantial Australian contribution can, as part of a wider international effort, resolve a development challenge. A research flagship was proposed that extends beyond support for Australian centres of excellence to important regional and international research centres.¹⁰

After consultations with the research community, AusAID published its first *Medical Research Strategy* in 2012.¹¹ The Strategy identified TB and malaria as priorities, and supported the

⁵ BHP Billiton Sustainability Report 2011.

⁶ WHO (2012), *Global Tuberculosis Report 2012*, Geneva: WHO.

⁷ The Hon. Julie Bishop address to ACFID Chairs and CEOs Dinner, 30 October 2013.

⁸ *Report of the Independent Review of Aid Effectiveness*, Canberra: AusAID, April 2011, Recommendation 23.

⁹ *Report of the Independent Review of Aid Effectiveness*, Canberra: AusAID, April 2011, at p.232, endorsing submission of the Nossal Institute for Global Health.

¹⁰ *Report of the Independent Review of Aid Effectiveness*, Canberra: AusAID, April 2011, pp.164, 176.

¹¹ See: <http://aid.dfat.gov.au/publications/Pages/medical-research-strategy.aspx>

funding of global Product Development Partnerships (PDPs) as the most effective way for Australia to contribute to medical research efforts in this field.

In June 2013, AusAID made its first allocations under the new *Medical Research Strategy*. In total \$10 million was allocated to TB and malaria PDPs. This is a modest allocation for a program area representing a potential new 'flagship' priority of the aid program. The \$10 million medical research allocation under the aid program is separate from the much more substantial research budget of the NHMRC (\$780 million in 2012-2013), which is focused on Australian researchers. AusAID's 2013 Annual Report indicated that \$40 million would be allocated to support the Medical Research Strategy over five years. Aeras believes that a funding allocation to the *Medical Research Strategy* of \$100 million over five years would establish medical research as a genuine flagship, enabling continued support to PDPs as well as contributions to new NHMRC initiatives in global health. As it stands however, with the January 2014 budget revision there is no certainty of *any* future budget allocations (beyond the initial 2012-13 allocation of \$10 million) to support implementation of the *Medical Research Strategy*.

The *Medical Research Strategy* prioritized mechanisms that are "globally competitive" and that "seek out the best research and researchers in the world." The *Medical Research Strategy* recognized that the PDP model meets these criteria, and therefore would deliver better value for money than an approach that exclusively funded Australian researchers. The PDP approach uses Australian researchers when they are the best for the job (as they often are) through the vehicle of PDPs that source the best expertise available internationally. For example, Aeras has been seeking to partner with Australian researchers to conduct epidemiological and clinical research to prepare for the possibility of future vaccine trials in PNG and Vietnam. PDPs provide a vehicle for domestic medical researchers to ensure their research translates into products that deliver tangible health impacts through new vaccines, diagnostics and drugs. However, as the leading PDPs are headquartered outside of Australia, they are generally not eligible for NHMRC grants – hence the importance of the Australian aid program establishing a new, separate funding stream for PDP support.

Support to PDPs that leverage private sector investments in research

Aeras welcomes the focus of the new Government on engaging the private sector in development. PDPs are an example of an effective mechanism for leveraging private sector engagement in medical research. PDPs such as Aeras conduct clinical trials at multiple sites across the globe and seek to engage research and product development partners who are leaders in their respective fields. For example, Aeras partners with academic research institutes as well as biotech companies in Australia, New Zealand and Japan, and international pharmaceutical companies such as GlaxoSmithKline. PDPs link academic researchers with biotech and pharmaceutical corporations, donors and global foundations such as the Bill and Melinda Gates Foundation. PDPs operate in high-impact areas of health and medical research, such as vaccines and drugs that are not being produced commercially due to market failure.

In a paper published in 2013, experts from the Australian National University's Development Policy Centre (Margaret Callan and Robin Davies) assessed the effectiveness of different approaches to engaging the private sector in development.¹² They highlight medical research PDPs as examples of public-private partnerships that conform with aid effectiveness principles:

¹² Callan, M & Davies, R 2013 "When business meets aid: analysing public-private partnerships for international development," *Development Policy Centre Discussion Paper 28*, Crawford School of Public Policy, The Australian National University, Canberra.

PDPs have a number of attractive features for donors. They are inherently outcome-oriented and have been quick to show good results. They are lean. They leverage substantial resources from big business. They usually manage a portfolio of projects, thus spreading risk (or “de-risking bets”). They concentrate expertise in a way that no individual donor agency could. They also allocate resources competitively and transparently to research institutions in both the developed and developing world, thus relieving donors of the burden of “picking winners”.

The justifications for funding of PDPs as an effective approach to engaging the private sector in pursuing medical research for global health priorities include:

- PDPs draw on global expertise from a range of partners including pharmaceutical companies, biotechnology companies, manufacturing partners, research institutes and NGOs.
- PDPs leverage resources and expertise from their partners, including in-kind donations of human resources and access to intellectual property.
- The approach of PDPs is to ensure new products that are acceptable and usable in developing countries. PDPs support uptake of products through engaging with governments of developing countries, local researchers, NGOs and local private sector partners.
- PDPs adopt a portfolio management approach, which increases the likelihood of success compared to funding single product candidates. PDPs are overseen by a scientific advisory group that ensures only the best candidates globally continue to be funded.

Funding of PDPs has suffered as a result of the global financial crisis. Globally, PDP budgets are under pressure due to reduced contributions from OECD donor countries. At the same time, more products are advancing to more costly stages of the development process. A phase 3 clinical trial, the last hurdle before product approval, can involve administering a vaccine to thousands of people in developing countries. It would be a serious setback to global product development efforts for TB, malaria and other diseases if Australia also terminates support to PDPs.

Conclusion

The development of new vaccines, diagnostics and drugs for TB and malaria should remain the clear priority for medical research supported by the Australian aid program. Funding for medical research under DFAT's *Medical Research Strategy* should be immediately reinstated in the 2013-2014 aid program budget and quarantined from future aid cuts so that it can be developed as a flagship area of the Australian aid program.

Australian researchers are playing a lead role in spearheading science and innovation. The Australian Government's continued leadership is required to support the *Medical Research Strategy* to further the partnerships between Australian researchers and global TB and malaria research efforts.

I would be happy to provide further information in relation to any of the above points.

Yours faithfully

John Godwin
Aeras, Australia Representative