

Submission to the Independent Review of Aid Effectiveness

Thank you for the opportunity to participate in the review of Australia's aid effectiveness. The following submission addresses AusAID's role in controlling tuberculosis (TB), the world's 2nd largest infectious killer, and a consequence and cause of poverty in low and middle income countries.

We recommend that AusAID invest in the development of new TB drugs in order to improve the effectiveness of bilateral and multilateral investments in TB control, and to bring about a sustainable, long term solution to this devastating disease.

Background on the TB Alliance

The Global Alliance for TB Drug Development (TB Alliance) is a global not-for-profit product development partnership (PDP) working to accelerate the development of new regimens to treat TB. Our goal is to develop new safe, effective and universally accessible TB medicines that are appropriate for resource-limited settings.

In participating in this review, our intent is to raise the profile of TB within AusAID's strategic priorities and promote the critical role of R&D in enabling the effectiveness and sustainability of TB control efforts.

The TB Pandemic: A global threat and a driver of poverty

TB kills one person every 20 seconds — nearly 5,000 people every day, or approximately 1.8 million in 2008 alone, according to the latest estimates from the World Health Organization (WHO). More than a century after *Mycobacterium tuberculosis (M.tb)*, the bacillus that causes TB, was discovered and a half-century after the discovery of antibiotics to treat the disease, TB is second only to HIV as the leading infectious killer of adults worldwide. The WHO estimates about one-third of the world's population is infected with *M.tb*. TB accounts for more deaths among women than all other causes of maternal mortality combined and is the leading infectious cause of death among people with HIV/AIDS.

TB devastates fragile economies, draining nations of scarce resources and robbing people with TB of health, hope and the ability to work and care for their families. TB attacks the poorest and most marginalized in all societies. It often strikes individuals in their most economically productive years and is expected to rob the world's most resource-limited nations of \$3 trillion over the next decade, thereby perpetuating the poverty cycle. Alleviating this health-related cause of entrenched poverty is an urgent development priority.

TB is a particular problem in South and East Asia, two regions of focus for AusAID. Together, these regions account for greater than half the global burden of TB and eight countries (Bangladesh, Cambodia, China, India, Indonesia, the Philippines, Thailand and Vietnam) are among the 22 high-burden countries designated as focus countries by the WHO. Of particular concern, growing drug resistance and co-infection with HIV is complicating TB control in these regions, further limiting programs' effectiveness.

The Urgent Need for New TB Regimens

New drugs are critical to ending the needless burden of TB. The current TB drug regimen, a product of scientific advances of the 1960s, requires six to nine months of treatment for active, drug-susceptible TB.

Unfortunately, many patients do not or cannot complete this treatment. Today's four-drug combination, taken ideally under daily monitoring, is burdensome for patients and care providers alike. Poor adherence and prescribing practices have led to the emergence of multi- and extensively drug resistant strains of TB (MDR-TB and XDR-TB) that increasingly defy current medicines and are spreading throughout many regions of the globe. Furthermore, the current TB drug regimen is not compatible with certain common antiretroviral therapies used to treat HIV/AIDS. Amplified by the consequences of poverty, today's epidemic is threatening to destabilize gains in TB control.

The promise of TB control efforts will only be fully met when patients and healthcare workers are given the best tools that modern science can deliver. The TB Alliance is accelerating the discovery and development of new TB drugs that will shorten treatment, be effective against susceptible and resistant strains, be compatible with antiretroviral therapies used for HIV/AIDS, and improve treatment of latent infection. Working with public and private partners worldwide, the TB Alliance is leading the development of the most comprehensive portfolio of TB drug candidates in history, paving the way for the first new treatments in over 40 years. The TB Alliance is committed to ensuring that approved new regimens are affordable and universally adopted so that novel drugs that treat TB more quickly and easily are available to all who need them.

The PDP Model: Maximizing donor funding

The TB Alliance is an example of a product development partnership (PDP), an innovative public-private model for developing and promoting accessibility of new health technologies for diseases disproportionately affecting poor countries. These not-for-profit entities leverage the resources and expertise of the public, private, philanthropic and academic sectors to accelerate the development of products that lack commercial profitability and may not otherwise be developed. PDPs employ a portfolio management approach, prioritizing the most promising and appropriate tools for continued development.

In the last decade, PDPs have markedly accelerated the development and adoption of new affordable and accessible health products in resource-poor settings. To date, PDPs and their partners have developed and gained approval of 12 products to mitigate the impact of diseases of the developing world. These entities have participated in developing 46% of the approved products to combat diseases of poverty, and, thanks to their establishment, the annual average of new products approved for neglected diseases has increased by 1.8 new products between 1975 and 1999, to 2.6 between 2000 and 2009. As indicated by London School of Economics, PDPs are achieving better health outcomes than either the public or the private sector working individually.

One particular advantage of this model is its ability to leverage donor funds with investments from the private sector. For example, the TB Alliance attracts investments from partners, thus augmenting support for its work and allowing the Alliance to conduct projects far larger than donor-provided funds would otherwise allow. Based on estimates of in-kind contributions over 2010-2011, every dollar of donor funding invested in a TB Alliance project will generate \$1.6 of value from the private sector.

Working for the public interest, PDPs are the only structures specifically developed to address financial barriers and create incentives for greater industry involvement in the development of pharmaceutical products for underserved populations. They also play an important role in linking the research initiatives with health systems working to control disease in the field. PDPs have established partnerships in developing countries most affected by these diseases to conduct clinical trials in relevant settings and facilitate the rapid adoption and uptake of new products, once they are available.

Investing in R&D through PDPs is an effective way to prioritize limited resources to those projects with the greatest potential for impact on public health. In fact, PDPs were created by major bilateral donors to harness the collective power of their investments to address this critical gap. Furthermore, PDPs are guided by independent scientific advisory groups, eliminating the need for donors who would not otherwise do so to employ in-house scientific expertise in order to oversee grant making in research.

Making Australian Aid More Effective: The promise of new TB regimens

To date, AusAID's funding for TB has largely been channeled through multilateral institutions such as the Global Fund. These investments support the development of robust, country-owned health systems capable of delivering essential medicines to their populations. With growing drug resistance to TB antibiotics and their incompatibility with commonly used drugs for HIV, however, it is clear that the current drugs are increasingly inadequate for addressing this evolving pandemic. Funding for TB control must be matched with investments in the development of new medicines that will allow all forms of TB to be treated safely and effectively in less time.

The role of new medicines is especially clear in addressing multi-drug resistant TB (MDR-TB). The WHO estimates that almost \$17 billion is needed between 2009 and 2015 to reach the goal of treating 80% of MDR-TB patients globally. This sum vastly exceeds funding available for the scale up of MDR-TB treatment. At between \$2,000 and \$9,000 per course, the high cost of MDR drugs is a major limiting factor. A new regimen in development by the TB Alliance, which could cost as little as \$300 per patient, would allow MDR programs to treat 1 million patients for the same cost of treating 150,000 patients today, saving health systems \$4b over 5 years in drug costs alone. Investments in the development of new regimens will save health systems in developing countries, and the donors that fund them, billions in TB control costs by reducing treatment times for resistant and sensitive strains and lowering the drug costs of MDR-TB treatments. In fact, if MDR-TB treatment scale-up follows current projections, the entire cost of developing a new regimen could be recouped in cost savings to TB control programs in the first year of introduction.

Summary

With TB raging in South and East Asia, increasing investment for this disease should be a major focus for AusAID as it reconsiders its aid priorities. Despite the heavy burden of disease in these regions, AusAID's funding for TB is relatively modest. A robust economic development strategy will not be complete without addressing the underlying factors that contribute to entrenched poverty, including poor health. As TB is one of the leading causes of sickness and death in these regions, economic advancement in Asia hinges on the ability to better control TB.

As AusAID evaluates strategies for increasing the effectiveness of its aid, it should strongly consider investing in the development of new tools that will enable health systems to perform better. New, shorter regimens for TB will reduce the burden on health systems to administer treatment by at least a third for drug sensitive TB cases, and by up to 75% for drug resistant TB. This will enable health personnel to reach more patients and improve the quality of care while at the same time reducing costs. Without new TB drugs, the lengthy and increasingly inadequate current treatment will continue to encumber TB control programs. A sustainable, long term approach to TB control must include investments in research and development alongside funding for delivery of current medicines.

The time is ripe for investing in TB R&D. The field of R&D for global health products has been strengthened in recent years thanks to investments by public and philanthropic donors. R&D is a long-term process that requires an investment consistent with the potential in order to yield end products.

However, donor interest in supporting product development for TB is slowing down, just at the time that the field is reaching maturity and is a close step to delivering valuable products to people. Now more than ever, donors, including AusAID, must invest in R&D for TB to ensure that new regimens come to market that are critical to reversing this major health and development crisis.