

Submission to the Joint Standing Committee on Foreign Affairs, Defence and Trade
Inquiry into the role of the private sector in promoting economic growth and reducing poverty
in the Indo-Pacific region

From the International AIDS Vaccine Initiative (IAVI)

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Context:

The International AIDS Vaccine Initiative (IAVI) is a global non-profit organisation working to develop vaccines to prevent HIV infection. As a Product Development Partnership (PDP), it works closely with private sector entities including major pharmaceutical companies, as well as with academic and governmental organisations, to catalyse research for which there is a clear need, but barriers discouraging private investment. Using the portfolio approaches which are common in the pharmaceutical industry, IAVI seeks to bridge the gap between the promising early-stage scientific research typically conducted in academia and the later-stage development and marketing of usable products conducted by the private sector, hence ensuring a steady pipeline of new products progressing through clinical trials. IAVI has a strong focus on developing countries, including in the Indo-Pacific region, where it works to build clinical research capacity and enable technological transfer.

This submission seeks to raise issues relevant to a variety of topics that will be considered in this specific inquiry, namely:

- The current role of the private sector in developing new healthcare products (such as vaccines) which help promote growth and reduce poverty in the Indo-Pacific region.
- The role of public-private partnerships in leveraging private sector investment and facilitating technical capacity building in developing countries.
- Risks related to current and possible future approaches to enhancing the role of the private sector in development, and their management.
- The role Australian and international businesses could play to support development and inclusive growth in partner countries.

IAVI is calling on the Government to:

- Recognise the critical need for new technologies to fight neglected and poverty-related diseases in the Indo-Pacific region and elsewhere, and the role that innovation can play in improving public health, reducing poverty and promoting economic growth.
- Recognise the distinct role that Product Development Partnerships (PDPs) can play in catalysing such innovation by facilitating partnerships between the public and private sector, both within and across partner countries.

- Support PDPs efforts to ensure the development of new prevention technologies to fight HIV/AIDS in the Indo-Pacific region and elsewhere, including the development of an effective AIDS vaccine.
- Make a renewed financial commitment to supporting product development, continuing and expanding PDP funding rather than letting it stagnate in the pilot phase, recognizing that long-term, predictable funding is critical to the delivery of new technologies, particularly vaccines.
- Ensure a focus on research investment into diseases that impose the greatest global burden, and that currently undermine Australian aid investments in the Indo-Pacific region.
- Support efforts to promote the development of new health technologies in partnership with the private sector in the post-2015 development framework.

The burden of diseases of poverty

Recent years have seen great progress in tackling deadly diseases in the Indo-Pacific region and elsewhere, but they continue to inflict a devastating toll on many countries. Worldwide, one death in three is from infectious or communicable diseases such as HIV/AIDS, TB or malaria; almost all of these in the non-industrialized world. Given the high financial costs associated with such diseases, and the fact that they often strike people during what should be the most productive years of their lives, their prevalence remains a serious obstacle to economic growth in many countries. Protection from infectious diseases is a basic precondition for growth and development; an essential first step in helping developing countries progress towards prosperity and self-sufficiency.

HIV/AIDS is a particularly striking example. Despite impressive progress in developing and then rolling out anti-retroviral medications, the disease continues to kill some 1.7 million people every year, and more than 6,000 people worldwide are newly infected with HIV every single dayⁱ. In the Asia-Pacific region, despite strong progress in some countries, HIV/AIDS remains a serious public health issue. AIDS-related deaths have not fallen at the same rate as in other regions.ⁱⁱ Around 350,000 people were newly infected with HIV in the region in 2012, nearly a quarter of them children and adolescents.ⁱⁱⁱ The number of new HIV infections has more than doubled^{iv} in countries such as Indonesia, where the government estimates that 6.4 million people remain at risk of infection.^v In the Philippines, the pandemic has accelerated at an unprecedented rate: from one new HIV infection every three days in 2000, to a new infection every three hours in 2011. HIV prevalence in that country is forecast to double by 2015.^{vi}

The drivers of the pandemic are numerous and complex, but one prevailing problem is that existing HIV prevention options have often poorly served populations most vulnerable to infection: women and young girls, men who have sex with men, people who use drugs, transgender people and commercial sex workers. Prevailing gender inequalities, stigma and

discrimination also often limit access to available health services. In the Asia-Pacific region, only half of people who are eligible for antiretroviral treatment have access to it; significantly below the global average.^{vii} Even in Australia, with near-universal access to treatment and healthcare, the number of new infections remains stable at around a thousand people per year.^{viii}

Perhaps most worrying of all, despite recent success in improving access to antiretroviral medication, HIV/AIDS is still spreading faster than the drugs to treat and prevent it: for every person getting access to treatment, more than one other is newly infected with HIV.^{ix} The economic burden imposed by HIV/AIDS on developing economies can also be crippling. HIV/AIDS tends to impose the most significant burden on adults of working age with the continuing high number of new infections representing a serious drag on economic growth in affected countries. The direct economic costs of HIV/AIDS are also formidable – according to UNAIDS, responding to the pandemic will cost a total of around \$25.8 billion per year from 2015 onwards in low- and middle-income countries alone.^x A successful effort to end the pandemic would therefore represent not only a profound social and moral victory, but an excellent financial investment: the elimination of a major cause of poverty and low productivity.

The need for new health technologies

One reason for the continued high economic and social burden of disease in the Indo-Pacific Region and elsewhere is the chronic lack of investment in the new tools needed to prevent, diagnose and treat diseases of poverty. Although people in developing countries bear some ninety percent of the global disease burden, it is estimated that only ten percent of worldwide expenditure on health is used to address these diseases.^{xi}

This disparity arises largely because diseases of poverty are, by definition, most prevalent among populations where there is limited capacity to pay for appropriate prevention and care. This leads to a lack of short-term financial incentives for the private sector to invest in developing health products for which there is profound need, but no immediately viable market. The results of this market failure are clear. Of the nearly 1,400 new medicines which were developed between 1975 and 2001, only 16 were targeted at diseases specific to developing countries.^{xii} Since 2001, only one percent of all new chemical entities approved for medical use were for neglected diseases, and only one percent of all clinical trials were for neglected diseases.^{xiii} Private pharmaceutical companies do excellent work in developing a huge range of innovative, life-saving products, but in the case of diseases such as HIV/AIDS, TB and malaria there remains a lack of incentives for them to invest. In 2012, only four percent of global funding for poverty-related disease research came from the private sector.^{xiv} In short, it is clear that market forces alone will not lead to the development of appropriate new products to tackle diseases like TB, HIV/AIDS and malaria.

This disparity between the need for new products and the levels of funding available to develop them is particularly acute in the case of vaccines. Vaccine development is typically a very long process, involving the development of numerous potential candidates which proceed through

clinical trials until one or more of them are proven to be safe and effective. Consequently, vaccines can take years to develop: the polio vaccine took 47 years to bring to market; the recently-developed rotavirus vaccine 33 years^{xv}. The costs associated with vaccine development are also significant, often running to hundreds of millions of pounds. This combination of long timescales, high capital costs and technical uncertainty mean that in the case of poverty-related diseases, vaccine R&D is seriously underfunded.

Vaccines to protect against HIV/AIDS are one example. Despite recent successes in rolling out anti-retroviral medication, an AIDS vaccine is still urgently needed: some 6,000 people are newly infected with HIV every day^{xvi}, and the pandemic continues to spread faster than the drugs which can treat or prevent it. However, only around three percent of all AIDS vaccine research funding comes from the private sector^{xvii}. *Left to market forces alone, vaccines to protect against diseases like AIDS and TB are unlikely to be developed.*

The role of PDPs in developing new health technologies

One important way of addressing the constraints which limit the private sector's ability to invest in developing new health technologies such as vaccines is via Product Development Partnerships (PDPs). Originally based on private virtual drug development models, PDPs are public-private partnerships which aim to accelerate the development of new products to prevent, diagnose or treat diseases of poverty. As not-for-profit organisations, funded mostly by government and philanthropic organisations, PDPs focus on filling gaps in the product development process - building partnerships between private sector scientists, governments, and civil society in order to catalyse research for which there is a desperate global need, but barriers to private investment. Typically, PDPs work on a portfolio basis: examining large pools of candidate products, and then accelerating the most promising ones through the development process, with the aim of ensuring a steady pipeline of new candidates starting clinical trials. They also usually have a strong focus on developing countries - the International AIDS Vaccine Initiative (IAVI), for example, partners with biotechnology and pharmaceutical companies with cutting-edge technology and expertise to accelerate vaccine design and development. It operates a network of research centres in Asia and Africa, with a strong focus on technology transfer and training local staff, helping ensure that an AIDS vaccine will be effective and appropriate for the most affected communities, and can be brought to market as quickly as possible.

Developing new medical products can take years, but the innovative approach of Product Development Partnerships has already scored several notable successes in developing life-saving products for use in countries where disease burdens are highest but serious constraints on commercial incentives exist. To date, PDPs have developed nineteen different products to tackle neglected diseases, including (for example) a new meningitis A vaccine, which helped reduce the incidence of meningitis by 94% in parts of Africa.^{xviii} More than 120 other products are currently

in development; including new drugs, vaccines and diagnostics for everything from TB, AIDS and malaria, to sleeping sickness and river blindness. As scientists' understanding of poverty-related diseases improves, a number of potential transformative products are now entering human clinical trials.

Engaging industry and stimulating private investment

PDPs have stimulated increased collaboration of the pharmaceutical industry to work on the diseases of poverty. As an example, IAVI stimulates private industry partnerships through financial investments, access to promising technologies, technical expertise and a clinical trials network, as well as the expedited regulatory reviews that are possible with HIV. With the creation of a hub for vaccine design and development in India, IAVI and industry, academic and governmental partners have created an initiative with enormous potential to attract private collaboration and partnerships in the Indo-Pacific region, likely to expand even more once targeted products enter into manufacturing phase.

As of May 2014, IAVI's key industry partners include 26 European, Asian, and US companies in the biotech and biopharmaceutical sectors. IAVI stimulates private industry partnerships through financial investments, access to promising technologies, technical expertise and a clinical trials network, as well as the expedited regulatory reviews that are possible with HIV. IAVI is diligent about securing IP rights for vaccine candidates in its portfolio to ensure freedom to operate so that a vaccine candidate can be developed without obstacles. Agreements with industrial partners ensure that the final product will be made accessible at reasonable cost and adequate quantity to those most in need of the vaccine. To date, IAVI has engaged 14 biotechnology companies through its Innovation Fund grants programme, which harnesses novel technologies outside the AIDS vaccine space. The New Alliances programme also ensures that selected technologies for which proof-of-concept has been established are then made available more widely for research purposes through Material Transfer Agreements, licensing and other arrangements. A further model of industry engagement includes in-kind contributions, e.g. logistical support or the provision of industry-specific expertise such as the successful Pfizer Global Health Fellows programme and GSK PULSE Volunteer Partnership.

Product development in the Indo-Pacific Region

IAVI is a good example of how public-private partnership can work in the Indo-Pacific region to accelerate AIDS vaccine development, which has been ongoing since 2001. The organization has been building and consolidating opportunities in the region in partnership with the Government of India, scientific institutions, international governments, non-governmental organisations and

civil society to ensure a comprehensive response to the HIV epidemic in India. India's thriving pharmaceutical industry and rich pool of scientists and medical professionals give it the potential to play a leading role in AIDS vaccine research and development. In order to ensure that this potential is realized, IAVI's India programme involves working in close partnership with the Government of India, the pharmaceutical industry and Indian academic institutions to build capacity for research and innovation in the country, as well as helping to establish global networks of excellence for biomedical research.

The aim is two-fold: to ensure that the India programme serves as the Regional Center of Excellence (CoE) for HIV vaccine R&D as well as acts as an integral contributor to IAVI's Neutralising Antibody Consortium (NAC), which is a hub that is driving regional South-South and North-South scientific collaborations for HIV vaccine research among emerging economies. Recent efforts have led to a significant growth of formal and informal relationships/collaborations that are helping the country promote Applied Research and Clinical Research initiatives into the larger Health Science Technology and Innovation agenda. It has also led to national ownership for long-term and progressive scientific endeavour, effective translational research and expanded global outreach.

This work includes a collaborative project between Indian and Australian scientists aiming to advance rational design of novel HIV vaccine candidates and improve existing influenza vaccines by studying antibodies which have the potential to eliminate virus-infected cells. A collaboration between Dr. Stephen Kent's group at The University of Melbourne and Dr. Madhuri Thakkar's group at India's National AIDS Research Institute is focused on obtaining robust information about the HIV-fighting antibodies present in populations in both India and Australia. By comparing samples which represent infections by different HIV subtypes, researchers can gain a far better understanding of the virus and how to fight it, than if they studied it in a single country alone. It is expected that the investigation will provide important information for future development of preventive vaccines designed to protect against the different HIV subtypes that exist across the Indo-Pacific region. It will also help determine how newly-identified antibodies might help clear hidden (or latent) forms of HIV in infected populations, one of the major barriers to curing HIV using currently existing drug therapies. The collaborative project also has promising implications for diseases other than HIV/AIDS. For example, examining the different responses of HIV positive populations from both India and Australia to influenza epidemics. By assessing how influenza affects HIV-positive Australians who have already received influenza vaccine, researchers hope to assist with the design of more effective influenza vaccines.

Public sector support

As discussed above, one of the key aims of Product Development Partnerships is to create opportunities for the private sector to innovate in fields where there would otherwise be limited financial incentives to do so. Their work therefore depends on developing close working relationships with pharmaceutical companies, including provision by those companies of both financial and in-kind support. However, as explained elsewhere, market failure means that in the case of products such as new vaccines to prevent infection with HIV, TB or malaria, public sector funding is essential to support their development, and catalyze investment from other sectors. International donors including the United States Agency for International Development (USAID), UK Department for International Development (DFID), and the Governments of the Netherlands, Germany, Norway, Denmark and Japan have a long track record of generous support for such product development (and except for Germany are also currently funding IAVI). Donors have viewed their support to be a sound investment: in 2010, for example, a DFID internal review of UK support for product development noted that “PDPs are achieving tangible results – notably rich pipelines of technologies in development and ten product launches since their start – and there are signs that they are stimulating ‘ripple effects’ [such as] capacity strengthening of clinical trial infrastructure... in developing countries”.^{xix}

However, the recent economic downturn, and subsequent cuts to development budgets, has led to downward pressure on many countries’ global health research budgets. A desire to focus on delivery and demonstrate the immediate impact of development spending has meant that projects which find it harder to generate immediate results – such as product development – have found themselves in a disadvantageous position compared to those which focus on delivering products and services which are already in place. As the 2013 G-FINDER report into poverty-related disease funding said: “Year-on-year funding to PDPs has been declining since 2009, but this year saw its largest cut so far ... down 20.0%”.

Unfortunately, these funding cuts have come at a time when many PDPs are reaching a critical point in the product development cycle, with products going into later-stage clinical trials – by far the most costly part of the development process. PDPs are therefore facing reductions in funding just as their own costs are rising – victims, perhaps, of their own success. These funding pressures mean there is a real risk that recent progress towards developing new tools to fight diseases such as TB and AIDS will now be undermined.

Australia’s role

Australia has a long track record of providing strong support to efforts to improve global health. In the case of HIV/AIDS, for example, the government has contributed US\$313M to the Global Fund since 2008, and recently made a very welcome commitment to maintain donations in the future^{xx}. AusAID’s work in health has also long been supported by a program of research.

Over the last five years, AusAID has invested over \$100 million in research to examine how to effectively strengthen health systems and deliver pro-poor health investments in low resource environments^{xxi}. The 2012 Medical Research Strategy confirmed that this type of health research would continue to be the priority for AusAID’s health program, to provide the evidence for current program needs and anticipate future knowledge requirements. In 2013, a total of AUS\$10m (US\$8.8m/€6.4m) was awarded as single-year grants to support PDPs working on new technologies to fight diseases including TB and malaria^{xxii}. Pre-election, the Coalition’s *Policy to Protect and Streamline Health and Medical Research Funding* also stated that “Australians can trust the Coalition to protect medical research funding as we have a clear record that demonstrates our support for this critical sector.”

However, there are now signs that funding will not be made available in future. In January 2014, DFAT reportedly stated that the 2013-14 budget for global health investments, including health research, is fully committed on government priorities, and they are as such unable to continue to fund medical research at this time.

Given the scale of public health challenges in the region that currently undermine Australia’s aid and development efforts in the Indo-Pacific region, this is extremely concerning and short-sighted. Cuts to product development funding not only risk undermining valuable research progress, but also seem to contradict the Coalition’s broader policies of supporting technological innovation and promoting regional partnership between the public and private sector. Recognising that innovative investment in product development is a sound aid investment, other donors such as the United States, United Kingdom and the Netherlands are renewing their own commitments to supporting product development, despite facing similar budgetary pressures. With numerous new products approaching human clinical trials, it seems misguided to cut funding just at the point when strong returns on investment might reasonably be expected.

Given the size and strength of Australia’s economy, and its history of leadership in both development and scientific innovation, the country has the potential to play a critical role in the development of new tools to fight the deadly diseases which continue to weaken the economic potential of countries in the Indo-Pacific. IAVI very much hopes that the new government will agree to do so.

ⁱ UNAIDS, Global Fact Sheet 2013

ⁱⁱ UNAIDS, ‘HIV in Asia and the Pacific’, 2013

ⁱⁱⁱ UN News, 19 November 2013

^{iv} UNAIDS, ‘HIV in Asia and the Pacific’, 2013

^v Indonesia National AIDS Commission, 2012 Progress Report

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- ^{vi} Philippine National AIDS Council, 2012 Progress Report
- ^{vii} UNAIDS, 'HIV in Asia and the Pacific', 2013
- ^{viii} UNAIDS, Australia Country Progress Report 2012
- ^{ix} UNAIDS, Global Fact Sheet 2013
- ^x UNAIDS, Investing for Results, 2012
- ^{xi} EDCTP, Research Into Poverty-Related and Neglected Diseases
- ^{xii} PRPP, 'New EU approaches to funding R&D for neglected diseases', 2005
- ^{xiii} The Lancet, October 2013
- ^{xiv} G-FINDER, 2013
- ^{xv} Vaccine R&D success rates and development times, Nature Biotechnology 14
- ^{xvi} UNAIDS Factsheet, 2013
- ^{xvii} G-FINDER, 2013
- ^{xviii} The Lancet, September 2013
- ^{xix} DFID, Product Development Partnerships: Lessons from PDPs established to develop new health technologies for neglected diseases, June 2010
- ^{xx} Global Fund, Pledges and Contributions, 2013
- ^{xxi} AusAID Medical Research Strategy 2012
- ^{xxii} Global Health Technologies Coalition, 21 August 2013