

2020-21 Federal Pre-Budget Submission

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Australian Federation of AIDS Organisations

The Australian Federation of AIDS Organisations (AFAO) is the national federation for the HIV community response in Australia. AFAO works to end HIV transmission and reduce its impact on communities in Australia, Asia and the Pacific. AFAO's members are the AIDS Councils in each state and territory; the National Association of People with HIV Australia (NAPWHA); the Australian Injecting & Illicit Drug Users League (AIVL); the Anwernekenhe National HIV Alliance (ANA); and Scarlet Alliance, Australian Sex Workers Association. AFAO's affiliate member organisations – spanning community, research, public health and clinical workforce – share AFAO's values and support the work we do.

The [Australian Federation of AIDS Organisations](#) (AFAO) welcomes the opportunity to provide a submission for the 2020-21 Federal Budget.

Background

AFAO welcomes the announcement from the 2019-2020 Federal Budget of \$45.4 million over four years to prevent, diagnose and treat sexually transmitted infections (STIs) and blood-borne viruses (BBVs). The Government's announcement will substantially strengthen the national effort to address BBVs and STIs. This already budgeted investment will assist Australia to meet its ambitious targets as set out in the eighth *National HIV Strategy 2018-2022* by allowing organisations to develop programs and initiatives that build awareness and provide HIV and STI education for key populations and emerging or hidden populations.

This submission outlines regulatory and systemic issues that threaten to impede Australia from achieving its goals of ending HIV transmission by 2022 as set out in the eighth *National HIV Strategy 2018-2022*. The adoption of the recommendations set out in this submission will ensure Australia is at the forefront of HIV prevention and continues to lead the world in the response to HIV. Without moving forward on these recommendations, Australia falls behind in its mission and leaves behind populations at risk of HIV. Australia must ensure all technology available to help end HIV transmission is made accessible to communities most at risk of HIV.

This submission highlights issues that relate not only to the response to HIV, but to community and not-for-profit organisations more broadly. The recommendations will enable organisations to become more sustainable and work more effectively and efficiently in achieving their missions. A strong not-for-profit sector is an essential part of a vibrant civil society and is critical in advising and supporting the Australian Government in its public policy goals.

Summary of Recommendations

Recommendation 1: That the Australian Government direct the Therapeutic Goods Administration to conduct a review of the advertising code governing therapeutic goods and make recommendations on any steps required to mitigate impediments to public health arising from the code.

Recommendation 2: That the Australian Government evaluates its requirement that the Therapeutic Goods Administration recovers costs from sponsors for its regulatory activities and considers alternatives to existing cost-recovery arrangements where these impede access to essential therapeutic goods.

Recommendation 3: That the Australian Government ensures infectious diseases, including HIV, other blood-borne viruses and sexually transmitted infections are recognised as strategic priorities by research funding bodies, including the Medical Research Future Fund (MRFF).

Recommendation 4: That the Australian Government set a ten-year target to grow Australia's investment in public health and prevention to five percent of the Health Budget.

Recommendation 5: That the Australian Government apply fair and uniform indexation of **\$350 million per annum** and match market wages to all grants and contracts for community sector organisations.

Recommendation 6: That the Australian Government resource reporting and evaluation of not-for-profit organisations' programs and initiatives.

Recommendation 1: That the Australian Government direct the Therapeutic Goods Administration to conduct a review of the advertising code governing therapeutic goods and make recommendations on any steps required to mitigate impediments to public health arising from the code.

Issues

Australia's first HIV self-testing device was registered by the Therapeutic Goods Administration (TGA) for use in Australia on 29 November 2018 and became available for consumers to purchase in Australia on 1 April 2019. The registration includes a set of conditions on the sale of devices to consumers. These include limiting sales to online purchases and through specialist HIV agencies (for example, AIDS Councils in states and territories and public sexual health clinics).

All registered medicines and medical devices are subject to the TGA's advertising code. The code ensures information provided about registered goods is accurate and allows consumers to make informed decisions, in consultation with their physician, without undue influence from industry. A consequence of this code is its reach into the public health education activities of organisations such as AFAO and its AIDS Council members. This is further complicated in the context of the HIV self-test and similar devices as, unlike pharmaceuticals, they are not a product that physicians prescribe.

Not-for-profit health promotion organisations working without industry interference to achieve public health objectives require clarity and flexibility in their operations. This includes in delivering education to consumers and communities about health issues and tests and treatments from which they may benefit.

The solution

At **nil cost**, the Australian Government could direct the TGA to review its medical devices and medicines advertising code and make any necessary recommendations that will ensure not-for-profit health promotion organisations are able to operate flexibly and without undue risk of penalty in providing health information for consumers and consumers for public health purposes.

Impact

The proposed changes to the TGA's advertising code will aid priorities set out in the Australian Government's eighth *National HIV Strategy 2018-2022*¹ including to end HIV transmission by 2022. They will align with the priority area of:

Improv[ing] the frequency, regularity and targeting of access to testing for priority populations and decrease rate of late diagnoses

And will also align with the key area for action concerning testing, treatment and management:

Expand the use and accessibility of a range of HIV and STI testing technologies and options and tailor testing approaches to the needs of priority populations and sub-populations, particularly where there is a need to improve early diagnosis

¹ Department of Health (2018). *National HIV Strategy 2018-2022*. DoH, Canberra. Available from: [https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/\\$File/HIV-Eight-Nat-Strategy-2018-22.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/$File/HIV-Eight-Nat-Strategy-2018-22.pdf)

Recommendation 2: That the Australian Government evaluates its requirement that the Therapeutic Goods Administration recovers costs from sponsors for its regulatory activities and considers alternatives to existing cost-recovery arrangements where these impede access to essential therapeutic goods.

Issues

There are significant initial and ongoing costs associated with registration and re-registration for industry to introduce new medicines and technology into the Australia market. While this is an essential step in Australia's regulatory framework to ensure safety and quality of new products, for technologies and medicines that are only required by small or targeted populations, the costs of registration and re-registration create a significant burden that disincentivises or impedes potential sponsors from entering or remaining in the Australian market.

The proportion of the Australian population that is impacted by HIV is small in proportion to the wider Australian population. Yet to achieve the Australian Government's goal of ending HIV transmission by 2022, timely access to established and new technologies is essential. The technology available to help the Australian Government end HIV transmission is advancing rapidly. Government requirements that the TGA recover from sponsors the costs associated with its regulatory role risk precluding new sponsors from entering the Australian market and exhausting existing sponsors' willingness to remain in the market. This has the potential to stymie Australia's world leading response to HIV.

AFAO is aware of several sponsors or potential sponsors who have indicated that commercial decision-making in relation to the Australian market is significantly affected by the high costs of TGA registration and re-registration. Registered HIV rapid tests administered at point of care and HIV self-test devices are at risk of being withdrawn from the market due to ongoing registration costs and quality control processes, post-market surveillance and market conditions imposed by the TGA's regulatory framework.

The solution

The Australian Government should evaluate its requirements imposed on the TGA for cost-recovery and consider alternative models where existing cost-recovery risks impeding the entry and retention of sponsors in the Australian market and therefore, access to essential therapeutic goods, including those required for public health purposes.

Impact of investment

This review will facilitate a more receptive environment for sponsors whose medicines or medical devices are appropriate for small or targeted populations in Australia. This will encourage sponsors' applications for registration and ease impediments that may cause sponsors with registered products to leave the Australian market.

Recommendation 3: That the Australian Government ensures infectious diseases, including HIV, other blood-borne viruses and sexually transmitted infections are recognised as strategic priorities by research funding bodies, including the Medical Research Future Fund.

Issues

The Australian Government's investment in the Medical Research Future Fund (MRFF) ensures that Australia stays at the cutting edge of medical research. The MRFF has the opportunity to support Australia's ongoing efforts to meet its target of ending HIV transmission by 2022 and further facilitate efforts to eliminate hepatitis C. Research that explores innovation in the prevention, diagnosis, treatment and management of infectious diseases including HIV, other blood-borne viruses (BBVs) and sexually transmitted infections (STIs) is essential in ensuring Australian's can achieve best possible health outcomes.

AFAO welcomed the inclusion of *communicable disease control* in the first MRFF Priorities and acknowledges the focus on communicable disease control has led to significant and necessary investment by the MRFF in research to develop safe and effective vaccines to fight infectious diseases of pandemic proportion. We are very concerned *communicable disease control* has not been retained in 2018-2020.

Australia is acknowledged internationally for its success in managing the HIV epidemic, from the early years to the present. This success has been underpinned by a 'social' public health approach, one that rejected the 'contain and control' model of traditional public health. Currently, Australia has access to biomedical interventions that can virtually eliminate HIV transmission and cure hepatitis C. This unprecedented opportunity will only be achieved through additional investment in research and surveillance.

The solution

The Australian Government should recommit to *communicable disease control* as an MRFF priority and act further on its pre-election commitment to "*continuing investment in essential research on hepatitis B, hepatitis C, HIV, and sexually transmitted infections and will work with the community to develop options for the prioritisation of initiatives through the Medical Research Future Fund (MRFF).*"

In recommitting to *communicable disease control* as an MRFF priority, the Australian Government should also support research that addresses infectious diseases not at pandemic proportion. For example, while there are highly effective treatments for HIV, and a range of behavioural and biomedical prevention strategies, nearly forty years into the epidemic there is still no effective vaccine or cure. In the case of another communicable disease, hepatitis B, there is an effective vaccine, yet the prevalence of hepatitis B among Aboriginal and Torres Strait Islander people is disproportionately high. This indicates the need for investment in social and behavioural research to better understand the contextual factors contributing to these higher rates. The Australian Government should support the Australian Medical Research Advisory Board (AMRAB) to conceptualise communicable disease through a 'social' public health model.²

Impact of investment

This investment will guide the already budgeted investment in research for HIV, other BBVs and STIs to develop options for the prioritisation of these research areas through the MRFF and assist with ending HIV transmission and elimination of hepatitis C in Australia. A 'social' public health approach that is attuned to the collective nature of epidemics, engages with affected communities and recognises that disease prevention and 'control' requires social and biomedical intervention and the engagement of affected communities to succeed. Applying this approach to communicable disease recognises that some infectious disease outbreaks require a sustained and multi-pronged response to enhance control.

² Mindal, A & Kippax, S. (2013). A National strategic approach to improving the health of gay and bisexual men: Experience in Australia. In S.O. Aral, K.A. Fenton, and J.A. Lipshutz (eds.), *The New Public Health and STD/HIV Prevention: Personal, Public and Health System Approaches*, Springer Science + Business Media, New York.

Recommendation 4: That the Australian Government set a ten-year target to grow Australia's investment in public health and prevention to five percent of the Health Budget.

Issues

The Australian Government spends in excess of \$77 billion on health per year with two percent designated for preventive health. Australia needs a long-term and sustainable economic response to the increasing costs of illness and health care through greater investment in robust, evidence-based preventive health initiatives.

Most parts of health have well-established financing arrangements, whether this is medical care through the Medicare Benefits Scheme, pharmaceuticals through the Pharmaceutical Benefits Scheme or hospital funding through federal and state and territory agreements. In contrast, funding for public health and prevention programs is often short term, project-based and rarely at scale; even for well-proven interventions. Sustainable financing of scaled-up and evidence-based public health interventions is essential if Australia is to realise the public health benefits of prevention programs.

The solution

The Australian Government increase investment in prevention to five per cent over a ten-year period. This should also be coupled with the implementation of a robust mechanism to guide decision-making on new investment in prevention alongside the continued and reliable resourcing of existing preventive health efforts.

Impact of investment

An increase in prevention spending in the Health budget allows for promising and proven prevention interventions to be funded at scale to achieve maximum public health benefit. This removes the need for the Department of Health to pursue uncertain financing processes on a case by case basis or identify savings elsewhere in Health for the scale up of proven programs.

Recommendation 5: That the Australian Government apply fair and uniform indexation of \$350 million per annum and match market wages to all grants and contracts for community sector organisations.

Issues

Government funds for service provision and grants are often not indexed year-on-year as they are awarded to or received by not-for-profit organisations. The absence of indexation makes it difficult for organisations to continue to provide the best possible services when funding recedes in real terms and expenses increase with inflation, ultimately impacting on the capacity of organisations to offer competitive wages. This strains organisations' capacity to continue to provide governments with the best possible value for money when they are required to continually do more for less. This has an impact on organisations' sustainability and their ability to attract highly qualified employees. Government funding for not-for-profit organisations should be based on relevant market wages for the skill sets required to perform the services the government has sought.

The solution

The Australian Government should invest **\$350 million** to offer fair and uniform indexation for community sector organisations and adopt recommendation 10.2 in the Productivity Commission's Research Report *Contribution of the Not-for-Profit Sector*³ that states:

In order to ensure that not-for-profits can sustain their workforces, and as wages are a major factor in the successful recruitment and retention of staff, Australian governments purchasing community services need to base funding on relevant market wages for equivalent positions. Costings need to take into account the skill sets required to perform the purchased services and be indexed appropriately to market wage growth within that industry sector.

Impact of investment

By adopting the Productivity Commission's recommendations, the Australian Government will benefit from a more efficient and effective not-for-profit sector that attracts highly skilled employees, has sustainable corporate services and allocates more time to the services that have been purchased by government.

³ Productivity Commission 2010. *Contribution of the Not-for-Profit Sector, Research Report*. Canberra. Available from: <https://www.pc.gov.au/inquiries/completed/not-for-profit/report/not-for-profit-report.pdf>

Recommendation 6: That the Australian Government resource reporting and evaluation of Not-for-Profit organisations' programs and initiatives.

Issues

Reporting and evaluation of programs and initiatives are often not programmed as part of funding and grant agreements between the Australian Government and not-for-profit organisations. Resourcing these activities relies on financially strained organisations allocating funds to these activities from other sources, including organisational reserves, or not at all. In order to ensure best practice, efficiency and effectiveness of programs and initiatives, the Australian Government should allocate funds for reporting and evaluation when undertaking funding or grant arrangements with not-for-profit organisations.

The solution

The Australian Government adopt recommendations 5.2 and 5.3 from the Productivity Commission's Research Report *Contribution of the Not-for-Profit Sector*.

Recommendation 5.2

Australian governments should adopt a common framework for measuring the contribution of the not-for-profit sector. Having regard to the diversity of the sector's activities and structures, measurement using this framework should embody the principles of proportionality, transparency, robustness, flexibility, and relevance.

Recommendation 5.3

To minimise compliance costs and maximise the value of data collected, Australian governments should agree to implement a reform agenda for reporting and evaluation requirements for organisations involved in the delivery of government funded services. This should:

- *commit to basing reporting and evaluation requirements in service delivery contracts on a common measurement framework (appropriately adapted to the specific circumstances of service delivery)*
- *require expenditure (input) measures to be based on the Standard Chart of Accounts*
- *develop data standards for the relevant non-expenditure items*
- *ensure that information generated through performance evaluations are returned to service providers to enable appropriate learning to take place and allow organisations to benchmark their performance*
- *employ, where practicable, the principle of 'report once, use often'.*

Impact of investment

The adoption of these recommendations will allow for improved relevance of data collection and evaluation quality to facilitate informed variations to programs and initiatives. It will ensure programs and initiatives purchased by the Australian Government through not-for-profit organisations are effective and that the public money to program funding is appropriate.