Joint submission to the Senate Standing Committees on Community Affairs

AUSTRALIAN FEDERATION OF AIDS ORGANISATIONS
Leading the community response to HIV

napwha national association of people with HIV australia

Therapeutic Good Amendment (2016 Measures No. 1) Bill 2016

Introduction

Role of AFAO and NAPWHA

As the peak national organisation for Australia's community HIV response, AFAO is recognised nationally and globally for the leadership, policy expertise, coordination and support we provide. Through advocacy, policy and health promotion, we champion awareness, understanding and proactivity around HIV prevention, education, support and research. AFAO provides a voice for communities affected by HIV and leads the national conversation on HIV. AFAO is particularly concerned to ensure communities affected by HIV are able to gain access to important medicines and medical devices as soon as possible, while simultaneously ensuring their safety and effectiveness.

The National Association of People with HIV Australia (NAPWHA) was founded in 1989 and is the peak organisation representing people living with HIV at the national level. Our members comprise State and Territory organisations of people living with HIV. Our focus is on policy and program advocacy to help ensure that Australia attains the highest standards in HIV prevention, treatment, care and research.

NAPWHA and AFAO promote the meaningful involvement, visibility and centrality of people living with HIV in all aspects of Australia's HIV response. We strongly endorse the goal of Australia's seventh *National HIV Strategy* which calls for the virtual elimination of HIV transmission in Australia by 2020.

Our interest in medicines and devices regulatory issues

AFAO and NAPWHA have a long history of involvement in regulatory issues concerning medicines, medical devices, health standards, clinical trials and scientific research. We work closely with clinicians, researchers and the pharmaceutical industry to ensure prompt access to important clinical trials and new medicines to treat and prevent HIV. This work includes interaction with Australia's prescription medicine and medical devices regulatory and funding processes.

The purpose of this interaction is to support the early availability of new HIV treatments and related medications and medical devices. We have also interacted with the regulator to highlight procedural barriers in the regulatory framework that delay or prevent products from entering the market where there is evidence that these products are safe and effective and may also provide a public health benefit.

The availability of HIV prevention medication, known as HIV Pre-exposure Prophylaxis (PrEP), is an example of this situation. PrEP is the use of HIV medication to prevent HIV acquisition. Research shows that it can reduce

the risk of acquiring HIV by up to 99%.[1] There are strong individual and public health benefits derived from PrEP.

The lengthy processes required for registration in Australia of the drug used for PrEP has complicated its access. This medication, known as Truvada, has been listed on the Australian Register of Therapeutic Goods (ARTG) since 2005 as a treatment for people with HIV and many thousands of people around the world have used it. When the manufacturer sought to have the same medication listed for HIV prevention they were required to submit a full application and follow standard timelines, even though Truvada had been approved for PrEP in the USA since 2012. **We welcome the prospect, as contemplated in this Bill, for the fast tracking of ARTG submissions of important new medicines and medical devices.**

The regulatory process for providing access to HIV rapid-testing devices for use by individuals – known as self-testing - is similar. Testing is critical to addressing HIV as it enables an individual to know their status and to take action to preserve their health and prevent onward transmission. Australian research shows that HIV self-testing among higher risk gay men doubled testing rates, while among infrequent testers, the rate of testing increased five-fold.[2]

A testing device that could be used for HIV self-testing is already registered on the ARTG for point of care testing in clinical settings, and also in community settings where they are administered by accredited peer test facilitators. The manufacturer is nonetheless required to submit a full application to have this point of care test registered on the ARTG for use as self-testing. Enabling this submission and process to be fast tracked would support the availability of a product on the market that has been shown to be safe and also highly effective.

We have a strong interest in seeing a more responsive TGA regulatory framework due to the significant public health and benefits that quicker access to PrEP and self-testing would provide in the form of substantial reductions in HIV transmissions. The operation of the TGA and the Pharmaceutical Benefits Scheme (PBS) are priority areas of interest for our work. We are strong advocates for consumer involvement in regulatory and funding processes for research, medicines and medical devices. AFAO and NAPWHA were major contributors to national advocacy in the early 1990s that resulted in the establishment of a streamlined clinical trial system and to improvements in the regulatory approval processes for medicines in Australia. These reforms have benefitted many people with life-threatening illnesses in Australia.

Regulation of medicines and medical devices – core principles

We believe that transparency and openness are core principles of effective medicines and medical devices regulation. Regulation should include making timely information available to the public in easy to access formats, as well as inviting input from the public at each significant step of the regulatory process.

Prompt timelines are essential for the effective regulation of new medicines and devices, especially as they relate to life-threatening diseases such as HIV, cancers, cardiovascular disease and diabetes. There are situations where there are strong individual and public health imperatives to providing medicines and devices as promptly as possible by prioritising and "fast-tracking" them through the regulatory system.

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1 The PROUD Study, Lancet 2016; 387: 53–60, Published Online September 10, 2015, http://dx.doi.org/10.1016/S0140-6736(15)00056-2

2 Forth Study: Lancet HIV 2017, Published Online February 16, 2017 http://dx.doi.org/10.1016/S2352-3018(17)30023-1

Response to the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

AFAO and NAPWHA note that this legislation is based on the *Expert Panel Review of Medicines and Medical Devices Regulation (2015)* and the Australian Government's response to that review (*Australian Government Response to the Review of Medicines and Medical Devices Regulation 2016).*[3]

We agree that the Expert Panel has provided a strong case for reform of the regulation of therapeutic goods in Australia.

We welcome the Government's response to the Expert Panel Review and note the statement that it understands that consumer, professional, and industry groups are looking for immediate action on reform. Therefore, we also welcome the Government's intention to commence work on designing implementation of the Review's recommendations, with a view to implementing early opportunities in 2016-2017.

We use selected headings from the explanatory memorandum to the Therapeutic Goods Amendment (2016 Measures No. 1) Bill as the framework for our submission:

1.1 New pathways for approval of medicines and medical devices

We welcome the proposed amendment of the *Therapeutic Goods Act 1989* to provide a legislative basis for the making of regulations to implement fast-tracking of applications for approval of new medicines and medical devices in Australia.

We welcome the legislation's intention to facilitate quicker access by patients to new medicines and devices that have significant advantages over existing medicines and devices.

We note that the operational details of these priority pathways are yet to be determined, but note that these will be the subject of extensive consultation before the regulations are made.

AFAO and NAPWHA welcome this commitment to extensive consultation on these new priority pathways, which will be essential to successful implementation. In light of the complexities and challenges involved with these regulatory changes, **we call for the establishment of a small, fixed term advisory committee, including consumer representation, to support and advise the TGA on the implementation of these important regulatory changes.**

NAPWHA and AFAO would also like to see the Bill amended to include public hearings of stakeholders as part of the regulatory decision making-processes, particularly concerning the regulation of important new medicines and devices. This would be in line with the practice of the US Food and Drug Administration (FDA) to encourage participation from all public stakeholders in its priority setting and decision-making processes (every FDA advisory committee meeting includes an open public hearing session, during which interested persons may present information or views orally or in writing). We believe that such hearings would provide Australian consumers, health professional and other parties with an opportunity to input the TGA directly concerning the regulation of important new medicines and devices.

[3] http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation

1.2 Variations to medicines through notification

AFAO and NAPWHA support this provision.

1.3 Enabling Australian 'notified bodies' to undertake conformity assessment of medical devices

AFAO and NAPWHA support this provision.

1.4 Enabling health practitioners to supply certain therapeutic goods not on the Register to patients under a notification scheme

AFAO and NAPWHA support this provision.

1.5 Review and appeal rights for persons applying to include new ingredients as permissible ingredients in listed complementary medicines

No comment.

1.6 Timeframes for decisions in relation to listed complementary medicines

No comment.

1.7 Strengthening Post-Marketing activity

NAPWHA and AFAO support a strengthened post-marketing surveillance system to help protect consumers, which includes all medicines and medical devices, as well as complementary therapies.

1.8 Amendments to TGA statutory advisory committees

NAPWHA and AFAO support this provision, but would like to see a commitment that there be a minimum of two consumer members appointed to these committees.

1.9 Schedule 1 – Variation of entries in Register to Schedule 5 – Permissible ingredients

No comments.

1.10 Schedule 6 – Approval of therapeutic goods, biologicals and medical devices

See comments in 1.1 concerning priority approval of therapeutic goods, biologicals and medical devices.

1.11 Schedule 7 – Time limits to Schedule 12 – Miscellaneous amendments

No comments.