



**Victorian AIDS Council  
Gay Men's Health Centre**

**including the Positive Living Centre**

VAC Reg. No. A 3609 GMHC Reg No. A0010550F  
VAC ABN 52 907 644 835 GMHC ABN 87 652 472 253

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Ms Lisa Studdert  
Head Market Authorisation Group  
Therapeutic Goods Administration  
PO Box 100  
**WODEN ACT 2606**

Ms Julianne Quaine  
First Assistant Secretary (Acting)  
Office of Health and Protection  
Department of Health  
GPO Box 9848  
**CANBERRA ACT 2061**

Dear Ms Studdert and Ms Quaine

**Re: The registration and sale of in-vitro diagnostic devices (IVDs) for self-testing (home testing) for the presence of human immunodeficiency virus (HIV) in Australia**

The Victorian AIDS Council/Gay Men's Health Centre ("VAC/GMHC") is the peak HIV/AIDS NGO in Victoria. The organisation's mission is to lead the fight against HIV/AIDS in Victorian by providing care and support for people living with HIV ("PLWH") health promotion, and advocacy. The organisation, with partner organisations, advocates to improve health outcomes for sexually and gender diverse communities.

VAC/GMHC supports a policy of regular HIV testing and early initiation of HIV treatment. In pursuit of these policies, VAC/GMHC supports the introduction of HIV self-testing in Australia. To ensure that this can occur, the following two reforms need to take place:

- Severing the section prohibiting HIV self testing devices contained the Therapeutic Goods (Excluded Purposes) Specification 2010; and
- Removal of the barriers that restrict community organisation from making representations about the product to our community.

The stimulus for improving HIV testing infrastructure is to bring the time from infection to diagnosis to zero. Currently in Victoria, the time from infection to diagnosis is 4½ years. VAC/GMHC strongly believes that the approval of HIV self testing devices is critical if the aim of reducing the time to zero is to be reached. If this aim is met, it will allow people to link more quickly with services to consider the benefits of treatment.

VAC/GMHC looks forward to working with the department to strengthen Australia's response to the epidemic.

Simon Ruth  
Chief Executive Officer  
Victorian AIDS Council/Gay Men's Health Centre

## **VAC/GMHC RESPONSE TO THE TGA PROPOSAL ON THE REGISTRATION AND SALE OF IN-VITRO DIAGNOSTIC DEVICES (IVDS) FOR SELF-TESTING (HOME TESTING) FOR THE PRESENCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN AUSTRALIA**

One of the primary concerns in addressing the HIV epidemic in Australia is the undiagnosed prevalence of HIV. It is estimated that the undiagnosed rate of HIV accounts for 50% of new HIV transmissions.

As a signatory party to the *2011 United Nations General Assembly Political Declaration on HIV/AIDS* (“UNPD”) Australia has committed to increasing the rates of HIV testing.

HIV self testing (“HST”) is a form of HIV testing that overcomes some of the impediments that have been identified as barriers preventing people at high risk of HIV from being regularly tested. Research shows that gay men and other MSM consider privacy, duration between test and result and the availability of different testing models as contributors to insufficient testing levels amongst populations at high risk of HIV.<sup>1</sup> VAC/GMHC believes that HST should be initiated to complement the series of available testing options

### **THE RISKS AND BENEFITS OF HOME-TESTING AS A MEANS TO ENABLE AND PROMOTE TIMELY HIV DETECTION AND INCREASE TESTING RATES OVERALL, PARTICULARLY AMONGST HARD-TO REACH POPULATION GROUPS**

#### **Benefits**

The strongest position a person can be in, is to know their HIV status. This enables the individual to mitigate the risk of acquiring HIV, or transmitting HIV to another party. In the absence of the knowing one’s status, an individual is in no position to implement the most effective HIV risk reduction strategies.

It is estimated that 10 – 20% of sexually active gay men and men who have sex with men have never been tested for HIV. Further up to 25% of these men have no testing plan or routine. HST is a form of testing that addresses the concerns many people at high risk of HIV identify as preventing more regular testing. These concerns include:

- privacy;
- duration between test and result;
- fear of being judged, and discriminated against, by the treating physician; and
- stigma.

Research shows that 2,018 gay men surveyed in 2009 expressed a strong preference for HST, with over 60% of men who have never tested for HIV, one of the target population groups that is most important to reach, indicating that they would test more often were they to have access to home based testing.<sup>2</sup>

Reducing the time between infection and diagnosis allows for newly diagnosed individuals to connect with services to consider the health benefits of commencing treatment, and also to minimise the risk of transmission through treatment initiation.

Australia’s response to the HIV epidemic is considered to be very successful however, we have fallen behind when it comes to HST. The UK, the USA, France and Singapore have introduced HST.

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<sup>1</sup> G Prestage, *The TAXI-KAB Study 2012*, The Kirby Institute

<sup>2</sup> G Prestage, *Pleasure and Sexual Health: The PASH Study*, 2009

Approving HST will allow community organisations like VAC/GMHC to support the use of HST in the community. Currently, this level of communication is restricted due to restrictions identified in the *Therapeutic Goods Act (1989)*.

## **Risks**

To manage these risks, the following information will need to be included on the package insert.

1. HST devices are screening tests. Any reactive result will require a confirmatory diagnostic test.
2. The window period for managing exposure to HIV needs to be carefully managed. Currently, this is 3 months.
3. As with all testing devices, there is a risk of a small number of false positives with HST. These issues are common to a number of self testing devices, such as home pregnancy tests and have been overcome with accurate information and education.
4. HST does not ensure linkage to care. Information about confirmatory testing and counselling needs to be localised so individuals can access support quickly and efficiently. The current system of using HST, which involves importing devices from overseas does not allow for this to occur.

## **Risk mitigation**

Advances in treatment have led to HIV becoming a chronic manageable infection. VAC/GMHC believes that gay men and men who have sex with men should have the same opportunity as people affected by diabetes, at risk of bowel cancer and women of reproductive age to take control of their health and wellbeing through the approval of modern HIV testing devices like HST.

VAC/GMHC has a history of successfully supporting communities and individuals at high risk of HIV in Victoria to make decisions that improve their health and wellbeing. This has been achieved by providing information in co-ordinated health promotion campaigns in addition to community engagement, peer education and outreach. Along with ASHM, AFAO and the other AIDS organisations in Australia, VAC/GMHC has the resources to support the community to use HST in the safest and most effective way.

To support community efforts to reduce risk with HST, VAC/GMHC believes manufacturers should provide mandatory point of sale education to consumers purchasing, or considering purchasing HST. This should include online video and other guides to support consumers. The information included in these videos would include information on confirmatory testing, window periods, and linkage to other local services.

## **THE RISKS AND BENEFITS OF ALLOWING TGA TO APPROVE SUCH DEVICES FOR HIV SELF-TESTING THAT ARE OF ACCEPTABLE SAFETY AND QUALITY AND PERFORM AS INTENDED TO INCREASE HIV DETECTION RATES IN AUSTRALIA.**

### **Benefits**

The current situation permits residents in Australia to import devices that have not been through a regulatory framework like the TGA. TGA approval will ensure that the best quality tests are available. This also allows for information on care and support to be localised and relevant to users in Australia.

## **Risks**

VAC/GMHC believes that the TGA's processes must be flexible enough to ensure the efficient and timely assessment and approval of HST devices. With technology continually improving, we expect that HST will improve at a similar rate in the future. This means that new devices will need to be tested and approved for purchase in Australia as quickly as possible to ensure that the benefits of HST are maintained.

### **Any limitations or conditions that should be placed on the supply of HIV self-testing devices**

As outlined above, VAC/GMHC believes that the impact of HST will be maximised where information and support is provided as a package insert with the HST device. This would allow for the best use of the devices and also the best outcomes for an individual who tests positive, in terms of linkage to care and support.

In the initial phase of HST approval, VAC/GMHC is of the view that HST devices should be in a number of places. This includes:

- Pharmacies;
- Sexual health clinics;
- Dentists; and
- Community organisations and online chemists.

This will allow for the community to familiarise themselves with HST, and the demands of the product in a supportive and non judgmental environment. This approach should come with a sunset clause, whereupon, the device should become more widely available.

In 2014, the epidemic of HIV/AIDS is poised on the brink of very exciting developments in the field of diagnostics, treatment and care. HST represents an important addition to current diagnostic tools that will provide more choice to individuals wanting to take control of their health and wellbeing.