BUILDING OUR COMMUNITY'S HEALTH & WELLBEING

6 May 2014

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**

ACON is New South Wales' leading health promotion organisation specialising in HIV and lesbian, gay, bisexual, trans* or intersex (LGBTI) health. Incorporated in 1985 as the AIDS Council of NSW, ACON has been widely recognised as an innovative, successful organisation which has adapted to changes in the HIV epidemic and responded early to emerging health issues among our communities.

ACON welcomes the opportunity to provide you with information relating to the availability of HIV self-testing devices in Australia. We strongly support the introduction of HIV self-testing in Australia and we believe the Australian Government should take all actions necessary to ensure timely access to safe, high quality, consumer friendly testing devices. This work should start with removing the prohibition on HST devices contained in the *Therapeutic Goods (Excluded Purposes) Specification 2010*.

We have addressed your specific questions in the attached document. We are confident that the availability of a range of self-testing devices will ultimately ensure better health outcomes for individuals, the Australian HIV response and the public good.

ACON looks forward to working with you to ensure the ongoing strength of the Australian response to HIV. Should you require any further information please contact me on [redacted] or email [redacted]

Kind regards

Nicolas Parkhill
**Chief Executive Officer**



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**ACON 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.**

HIV has been, due to advances in treatment, a manageable chronic disease for a number of years in Australia. There is little justification for not affording gay men, the most at-risk population for HIV, the same opportunity as people affected by diabetes, people at risk of bowel cancer or women of reproductive age the same opportunity to take control of their health through approval of HST.

There are a significant proportion of people with undiagnosed HIV in Australia. It has been estimated that undiagnosed HIV accounts for around 50% of new HIV transmissions. Gay men and other men who have sex with men (MSM) constitute around 80% of new diagnoses in Australia.

Research amongst gay men and other MSM have identified barriers to testing that include privacy, time and the availability of tests. HIV self-testing (HST) has been identified as an acceptable way of overcoming some of these barriers. We see HST as part of a comprehensive testing regime that will facilitate a reduction in the proportion of people living with HIV who are undiagnosed. Below we have responded to the specific issues you have sought feedback on, and included mitigation strategies for the risks identified.

The importance of increasing the rates of HIV testing are recognised in the *NSW HIV Strategy 2012-2015*; the draft *National HIV Strategy 2014-2017*; and the *2011 United Nations General Assembly Political Declaration on HIV/AIDS* to which Australia is a signatory. To achieve the personal and public health benefits of timely diagnosis and initiation of treatment, along with these goals, action must be taken to remove the barriers to testing that have been identified by at-risk populations, including through the introduction of HST devices. This action is in line with consumer-centred health principles and in keeping with advancements in other areas of health, including diabetes, reproductive health and bowel cancer.

Australia has had a static HIV testing model in place until recently, which required a visit to a clinician for an HIV test and a follow up visit a week later for the results. Recent advances in science and technology has resulted in an expanded range of safe, high quality, consumer friendly testing devices being available in other jurisdictions. We believe that access to HST in Australia should be implemented to contribute to the series of testing options available, including accessing a clinician for a blood test or rapid tests performed in a range of settings, including in community settings. Access to a greater range of testing options also requires an updated framework and we urge the Australian Government to implement a framework for HST that ensures efficient and timely assessment and approval of devices. This updated framework should maintain a commitment to voluntary and confidential testing.

It should also be noted that access to HST devices will mean that consumers an option to buy their own tests, an option that is not currently available. This will assist in increasing HIV testing rates, while not increasing costs to the public health system.

**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**

Gay men and other MSM in Australia have historically reported comparatively high rates of HIV testing compared to similar jurisdictions but more testing is required in order to quickly identify undiagnosed HIV infection.

Increasing the proportion of gay men and other MSM who test regularly and are aware of their HIV status is critical to good health and to meet our commitments to reduce infections, in line with the *2011 UN Political Declaration on HIV*, and the goals of the *NSW HIV Strategy 2012-15*.

Research tells us that around 10 – 20% of sexually active gay men in Australia have never been tested for HIV and that this figure is slowly increasing. Up to a further 25% of these men have no regular testing routine. It is also estimated that a large minority of HIV positive people may be unaware of their infection. The introduction of HST may assist in lowering the threshold to testing access for those who have never tested.

There is a need to reduce the average time from infection to diagnosis, which is currently 4½ years in NSW. The *NSW HIV Strategy* has a target of reducing this average time to 1½ years. This reduction in time between infection and diagnosis of HIV will allow people to connect more quickly with services, commence treatment and improve their health. The availability of HST is likely to encourage men to test in the privacy of their own home, and via appropriate information and support, facilitate entry to the health system.

Research amongst gay men and other MSM have identified a number of barriers to testing including the opening hours of health care providers, the time it takes to receive results, privacy, the difficulty of finding a supportive GP, stigma, and the risk of discrimination. Approval of HST is likely to address a number of these barriers by allowing people to undertake the test in the privacy of their own home and receive test results in less than 30 minutes.

Australian research conducted among 2,018 gay men in 2009 offers clear evidence of a strong preference for home testing, with over 60% of men who have never tested for HIV (one of the most important groups to reach) indicating that they would test more often were they to have access to home based testing (*Pleasure and Sexual Health: The PASH Study, 2009*).

Providing gay men and other MSM with access to HST devices will be providing a form of testing that they have identified as being a desired form of testing that would improve their testing routines. The CONNECT Study 2012, undertaken by the Kirby Institute, shows that home rapid tests were the most preferred form of testing identified by gay men in the study. The study also showed that rapid tests were preferred over standard tests and that community and home based settings, rather than clinics and at GP's were the preferred location of testing. These findings point to a very strong preference for the availability and use of HST devices and are consistent with other Australian and international studies on home based testing amongst gay men. Importantly access to HST is in keeping with consumer centred approaches to health care.

Australia has historically been at the forefront of the response to HIV, yet on access to HST devices we fall behind other jurisdictions, including the UK, the USA, France and Singapore. We believe that

access to HST is overdue and the framework for availability must be rapidly developed and implemented to ensure that Australia does not fall further behind.

Diagnosis allows people to take steps to minimise their risk of transmission, through starting treatment and maintaining an undetectable viral load, taking preventative measures, and employing risk reduction strategies. Access to HST will likely increase the rates of testing and allow people to make choices about treatment and the preventative measures they take to reduce transmission.

Approval of HST devices will allow community based organisations, like ACON, to communicate with gay men about the use, limitations and service links that ought to accompany their use. This communication is not currently possible due to restrictions contained in the Therapeutic Goods Act (1989), even though we understand that kits are being purchased over the internet or from overseas and used in Australia. Registration of HST devices will remove this restriction and allow us to communicate to consumers more effectively.

**Risks**

HST devices are screening tests and not diagnostic test, so any positive result will need to be followed up by a confirmatory diagnostic test. Information on confirmatory testing and window periods needs to be included in package inserts by the manufacturer. This should be a requirement that a manufacturer needs to meet before the TGA approves a HST device.

Tests results will be interpreted by the person undertaking the test, a person who may not have much experience in reading test results. HST devices also deliver a small number of false positive and false negative results, something that is common to other forms of testing, though at different rates. These are issues common to a number of self-testing devices, such as home pregnancy tests, and these risks have been overcome through accurate information and education.

Consumers may not engage with appropriate care and support services, but no test can ensure linkage to care. Local information and education must be provided to ensure maximum linkage to care, such as confirmatory testing and counselling. The current situation where HST devices are only available via self-importation or online currently does not allow for this information to be provided.

HST devices may present problems to the collection of surveillance data, though this is more of a risk with unapproved imported devices. The regulation of HST devices will at least enable the collection of sales data, something which cannot happen under the current circumstances where HST devices are imported or purchased online.

**Risk mitigation**

Many of the risks outlined above can be addressed through health promotion and education. This will require community organisations, health care providers, and manufacturers to play an active role in minimising any risks.

Community organisations, like ACON, will play a key role in educating our communities about the use of HST devices. ACON has recently applied to the TGA to make restricted representations under

*section 42DE* of the *Therapeutic Goods Act (1989)* about HST devices, including their risks and how to access appropriate care and support.

ACON will play a key role in educating the community about access appropriate care and support if required. ACON has a proven track record of delivering tightly focused messages to its communities and we are confident in being able to communicate appropriate information about HST devices. This information will be focused in gay community media and online in targeted forums. We see organisations such as ours advising consumers to seek confirmatory testing and to discuss risks and outcomes with their doctor or a sexual health clinic.

In addition to general information provided by community organisations, health professionals will play a key role in making sure the limitations of HST devices are understood. Medical professional bodies, general practitioners, doctors and chemists will be essential to ensuring accurate medical information is provided to consumers.

The risk mitigation strategies outlined above can be provided through existing partnerships across the HIV sector. Organisations such as the Australasian Society for HIV Medicine (ASHM), the Australian Federation of AIDS Organisations (AFAO), ACON and other AIDS councils have the mechanisms in place to talk to communities and to health professionals. These will be utilised to ensure that each organisation's constituencies are informed of the availability of HST, and the information needed to safely and confidently use HST devices.

The TGA should require manufacturers to provide point of sale education on the use and interpretation of results provided by HST devices. Local information must be contained in the package insert for each HST device sold. This should include important and accessible information on how to use the device, window periods, 24 hour telephone support and contact details for local services. This condition was applied by the US Food and Drug Administration (FDA) on the first HST devices that they approved and we expect that equivalent authorities in the UK and France will require such information in the devices approved for sale in those countries.

Online platforms of the manufacturers and at the point of sale will provide a unique opportunity to give consumers information relating to the proper use of HST devices in addition to mandatory package inserts. This could include the use of video and other guides to support consumers in the use of devices. Videos already exist for HST devices approved in other jurisdictions, similar to those supporting the use of home pregnancy tests and bowel cancer screening tests. This online information should also include extended 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 TGA will play a key role in ensuring the quality of HST devices available for use in Australia. Currently individuals are able to import devices for their personal use and they can be of variable quality and accuracy, as they haven't necessarily been through rigorous assessment by an equivalent competent authority and may not provide an accurate screening test. By the TGA approving such

devices they will be ensuring that better quality tests are available compared to what is currently available on line.

The approval of devices may allow for more accurate surveillance data to be collected on the number of people testing and the number of devices used, this will primarily be through sales data but other methods of data collection could be explored by state and territory jurisdictions, such as the collection of voluntary online data from users of HST devices.

Manufactures should be required to provide local and reliable information about HIV, care and support. ACON has seen examples of HST devices ordered over the internet where there was no local information supplied with the device. One kit referred people to generic and unreliable sources of information about HIV, including Wikipedia. T

**Risks**

The TGA process put in place must ensure the efficient and timely assessment and approval of HST devices. With HST devices having improved in accuracy and quality over the past few years, we presume that they will advance at a similar rate in the future. This will make the timely assessment of new devices vitally important to ensure the highest quality devices are available for purchase in Australia. This will also lessen demand for HST devices purchased online or overseas.

We cannot identify any risks beyond the risks outlined above. We believe that taking into consideration the risk mitigation strategies above will ensure an acceptable and safe framework with which to introduce HST devices into the Australian market. The introduction of HST in other jurisdictions has been based on assessment that the public health benefits outweigh the individual risk, an assessment with which we agree.

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

Manufacturers should also provide information on how and where to get follow up support and advice as a package insert with the HST device. This would allow for best use of the devices and maximise linkage to care.

To achieve improvements in personal health along with increases in testing and a decrease in the time between infection and diagnosis, ACON would initially like to see HST devices available in number of places including chemists, clinics, dentists, community organisations and online chemists. This would allow the community to become familiar with the product in environments that provided maximum support. This should be time limited with a view to wider availability of devices into the future.