NSW GOVERNMENT | Health

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Ms Julianne Quaine
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Dear Ms Studdert and Ms Quaine

Re: The registration and sale of in vitro diagnostic devices for self-testing for HIV.

Thank you for the opportunity to provide feedback on the proposal to allow 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.

In summary, the NSW Ministry of Health supports regulatory change by the Therapeutic Goods Administration (TGA) to allow the registration and sale of self-testing devices for HIV in Australia. This will facilitate access to self-testing as part of a range of strategies that need to be in place to increase HIV testing. Frequent testing for HIV leads to early diagnosis which enables early treatment for individual health benefit and to prevent onward HIV transmission. Making testing more accessible will make it easier for high risk people to test, and to test more often. This is a key component for achieving the treatment and prevention targets adopted in the *NSW HIV Strategy 2012-2015;* draft *National HIV Strategy 2014-2017*; and the *2011 United Nations General Assembly Political Declaration on HIV/AIDS*.

The NSW Ministry of Health's response to the proposal by the TGA is detailed in the attached document.

Should you require any further information regarding the NSW Ministry of Health's submission, please contact [redacted] HIV and STI Branch, Centre for Population Health on [redacted]

Yours sincerely

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16/5/14

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NSW MINISTRY OF HEALTH, CENTRE OF POPULATION HEALTH, RESPONSE TO THE PROPOSAL TO ALLOW THE THE REGISTRATION AND SALE OF INVITRO DIAGNOSTIC DEVICES (IVDS) FOR SELF-TESTING (HOME TESTING) FOR THE PRESENCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN AUSTRALIA

High quality, safe and appropriate rapid testing devices, including self-testing devices, would provide a valuable contribution to a comprehensive and innovative strategy for HIV testing which includes both screening and diagnostic tests. NSW supports regulatory change by the TGA to allow the registration and sale of self-testing devices for HIV in Australia under a model where self-testing is self-funded and key information about the performance characteristics of the test and the need for confirmatory testing are provided to the user in plain English with the sale.

Although self-testing devices for HIV cannot currently be supplied in Australia, anecdotal evidence indicates they are being individually imported from overseas for personal use. As acknowledged by the TGA, the quality, safety and performance of these devices has not been evaluated by the TGA, or in some cases any regulator and this situation poses a significant risk to individual and population health. The Ministry expects a rapid escalation in the use of self-testing devices individually imported from overseas, and people with reactive results from imported rapid self-tests kits have begun to appear in notification data in NSW. Therefore a timely response to this issue is required.

In NSW, a significant proportion of people infected with HIV are undiagnosed and do not know they are infected. Despite the introduction of innovative models of care and testing scale up, the gay periodic survey shows that only 76% of people report having had a test in the past 12 months suggesting there is still unmet need. Undiagnosed individuals are at higher risk of developing HIV related morbidities. Critically, they pose a risk of transmitting HIV to others, contributing approximately 50% of new infections in Australia annually. Increased testing is essential for early access to treatment and reduced HIV transmission. Significant increases in the rates of testing are required to achieve the targets adopted 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.

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

There are significant benefits to be gained from utilising self-testing within a comprehensive HIV testing framework to increase access and frequency of testing amongst harder to reach population groups, as it overcomes many traditional barriers to conventional testing. Although there are some risks associated with self-testing devices for HIV, these can be largely mitigated through the implementation process. The Ministry has identified major benefits and risks.

Benefits

- Self-testing devices have a high potential to meet the needs of populations at high risk of HIV infection, or individuals in situations with ongoing potential exposure, e.g. those in serodiscordant relationships.
- Self-testing devices also have a potential to meet the needs of other populations that are underserved or marginalised by conventional testing services including people located in rural and remote areas of NSW.

- Self-testing devices, used as a screening tool, are likely to be effective in overcoming identified barriers to conventional means of HIV testing[1] by increasing access, supporting autonomy, providing added confidentiality and privacy, and convenience.
- The availability of self-testing devices is expected to result in increased testing and/or frequency of testing, which can make an important contribution to earlier diagnosis of infection, entry into care, concomitant reduction in morbidity and onward transmission.

Risks and limitations

- Self-testing devices are a valuable screening tool rather than a definitive diagnostic instrument. There is a risk that users may
    - Not undergo confirmatory testing and link into appropriate care after receiving a reactive result.
    - Be inappropriately reassured by a false negative result.
    - Experience unnecessary emotional distress from a false positive result.
    - Incorrectly use the test or interpret the result, resulting in a delay in seeking care and/or an increased risk of transmitting to others.
    - Use repeated self-testing as a substitute for risk reduction.
    - Not fully understand that the results of the test are not a definitive diagnosis.

  The risks identified will be averted or minimised by providing reliable, accurate and accessible information on self-testing for HIV with the device to ensure users understand the purpose and limitations of the screening devices, as well as promote locally available support services such as a health information phone lines to enable linkage to care and support services.
- Self-testing devices have lower sensitivity than conventional tests, especially during seroconversion. This risk can be mitigated by informing users with negative test results and recent/on-going risk of the necessity to re-test frequently (even monthly).
  Self-testing has been approved in other contexts such as the US and the United Kingdom on the basis of findings that showed the public health benefits outweighed individual risk associated with reduced sensitivity.
- Self-testing devices also have a lower positive predictive value than conventional tests, particularly in low prevalence populations. This risk can be mitigated by linking users with a reactive result to confirmatory testing services to exclude a false positive result.
- Testing for HIV must remain voluntary and confidential and free from any form of coercion. This principle applies to all forms of HIV testing.

The risks and benefits of allowing the 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

- In addition to the significant benefits identified for self-testing devices overall, TGA approval of self-testing devices is likely to reduce the importation of unregulated self-testing devices and ensure that only devices which deliver on quality, safety, performance and ease of use, are available in Australia.
- TGA registration will be important in mitigating the risk of inadequate and/or inaccurate information that is currently associated with some imported self-testing devices, by requiring that consumers are provided with reliable, accurate and locally relevant information when purchasing self-testing devices, including information on optimum use of devices, the window period, how and where to seek confirmatory testing, and how to link into appropriate care and support services.
- TGA requirements for the sale of devices would allow for improved monitoring of the number of individuals tested and/or number of devices used.

[1] Barriers commonly identified to conventional HIV testing include: the need to attend a health service to access a test, time taken for test results to be available, poor access to health care providers, confidentiality concerns and privacy, stigma and risk of discrimination.

- TGA requirements for the sale of devices would allow for improved monitoring of the number of individuals tested and/or number of devices used.

Risks

- There are few risks over and above those identified for self-testing overall.
- Although linkage to care, including counselling or referral for first time users is not ensured, it must be noted that no HIV testing program can guarantee this. There is no evidence from other jurisdictions where HBT is approved that use of HBT devices will reduce a person's access to professional healthcare.
- Although TGA registration of self-testing for HIV may imply support for self-testing for other serious conditions such as those in the Therapeutic Goods (excluded purposes) Specification 2010, this risk can be mitigated by making it clear during implementation that HIV is an exception to this principle.

Conditions or limitations that should be placed on the supply of HIV self-testing devices

- It is important that ease of use for the general population, in addition to test performance, is given consideration during the approval process as this will have a considerable impact on uptake and human error.
- Close consultation with State/Territory jurisdictions and the affected communities will be important. Conditions should not be so complex and onerous as to diminish the availability of self-testing.
- A framework to support the implementation of self-testing devices for HIV in Australia will be required. The framework should address
    - Locations or mechanisms by which the devices can be obtained. NSW recommends that self-testing devices should initially be available from a range of locations to facilitate ease of access such as over-the-counter at pharmacies, clinics, and community-based health organisations, with the option to purchase in person as well as online, by mail or by telephone.
    - The required communication and education for users, clinicians and those selling the device, including pharmacists.
        - Packaging must meet TGA requirements and reflect the Australian context. In particular, consumer information should include messaging in plain English on how to use the test, the need for interpretation, referral to local services for confirmatory testing and treatment, limitations of the test including the window period and requirement for repeat testing, reputable Australian sources of further information, safe sex and safe injecting messages, and referral information for local services. The national bowel screening program provides an appropriate model.
        - Innovative strategies to deliver supplementary information and support including an online video or DVD demonstrating how to use and interpret the test should also be encouraged.
        - The manufacturer should also provide information to be available at the point of sale, but should not be required to deliver training to all stockists on using and interpreting the device.
        - It would be important to consider cultural complexity and accessibilty in how information is accessed.
    - Linkage to care
        - It is important to facilitate linkage to care to facilitate confirmatory testing.
        - The provision of support to individuals who have undergone or are about to undergo a self-test for HIV. There are a number of existing telephone services, including healthdirect and the NSW Sexual Health information line. Self-referral to appropriate services that provide 24 hour access, such as healthdirect, should be supported.