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Dear Dr Hobbs

Subject: Consultation - Proposed performance requirements for tests to detect the presence of human immunodeficiency virus (HIV)

Thank you for your letter of 25 November 2014 to Dr Roscoe Taylor, Director of Public Health, seeking the view of the Tasmanian Department of Health and Human Services on proposed performance requirements, risk mitigation strategies and conditions of approval for sale of tests to detect the presence of human immunodeficiency virus (HIV). Your letter was accompanied by a consultation paper entitled "Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests".

The letter also came to Dr Scott McKeown (Tasmanian representative on Blood Borne Viruses and Sexually Transmissible Infections Subcommittee) and to me in my role as Tasmanian representative on Communicable Disease Network Australia. This response incorporates our views.

We provided a response to your letter dated 15 April 2014 seeking initial comments on a proposal to allow the registration and sale of HIV self-testing kits. Some of the earlier response remains apt, but here we respond to the specific questions in the current consultation.

Performance requirements

We support the principle that all tests for HIV should demonstrate the highest possible standard of performance compatible with the intended purpose of the test, and with regard to the setting in which the testing is conducted. The consultation paper clearly articulates that performance requirements depend on the intended purpose of the test, the format of the test, the intended user of the test, and the specimen type. This means that there are differences in performance requirements for HIV laboratory testing, HIV Point of Care Testing (PoCT), and HIV self-testing.

Assured access to high quality, safe and well performing HIV testing is an essential underpinning for the *7th National HIV Strategy* priority action to increase the uptake of appropriate HIV testing among people from priority populations, particularly gay men and other men who have sex with men. However HIV self-testing outside of high prevalence populations is likely to result in a relatively high number of false positive results. This will cause distress until the result can be resolved. This may be addressed by ensuring that carefully and simply expressed information about positive self-test results is provided in the product information, and as part of the wider discourse on the use of such products. This is very important.

Risk mitigation strategies

HIV PoCT

We support the current product specific conditions (risk mitigation strategies) for HIV PoCT registered in the Australian Register of Therapeutic Goods (ARTG) as detailed in the consultation paper. We do not have any suggestions for amendment or additional measures regarding HIV PoCT.

HIV self-testing

We agree that HIV self-testing requires both a well performing and a highly useable test kit. In the absence of clinical expertise, appropriate testing "at home" requires access to plain language information (including in languages other than English) regarding:

a. performing the test, and interpreting and understanding the result;
b. the significance of a positive test result and the need to consult a medical practitioner;
c. the significance of a negative test result if recent or ongoing high risk behaviour;
d. the need for persons at risk of HIV to also access testing for other STIs; and
e. prevention of HIV transmission.

This information should be provided in multiple forms of media, including written format in plain language and in languages other than English, on-line videos and by providing a 24-hour support and counselling service. Access to this information should be provided at the point of sale, within the packaging of the device for use at home, and to those selling devices.

Additional risks associated with HIV self-testing not detailed in the consultation paper include the following:

a. *Potential consequences for public health surveillance of HIV infection if confirmatory testing is delayed or does not occur.*

   HIV self-testing may have consequences for public health surveillance of HIV infection if confirmatory testing is delayed or does not occur. Information provided with the test kit and by the 24-hour support and counselling service should facilitate accessing confirmatory testing of positive test results. The 24-hour support and counselling service should offer a voluntary recall and reminder service to support a person with a positive HIV self-test result to access confirmatory testing.

b. *The absence of clinical processes involved in conventional HIV testing to identify and manage a person who knowingly places others at risk.*

   HIV self-testing "at home" will not involve clinical processes to identify and manage a person who knowingly places others at risk unless such a person with a positive test results proceeds to a clinical encounter for confirmatory laboratory testing. Failing to engage and support such a person may poses a public health risk. Information provided should reinforce the responsibility of a person with a positive HIV self-test result to prevent possible transmission until their definitive HIV status is determined by confirmatory testing.

c. *The potential for such tests to be used for non-clinical purposes; such as in insurance, occupational or other contexts; or surreptitious use to test an unsuspecting, uninformed and non-consenting person.*

   Measures should be considered to mitigate the possibility that HIV self-test kits are used for non-clinical purposes or surreptitious testing.

Conditions for approval

It is important to consider how risk mitigation measures may be achieved through conditions for sale of HIV self-test kits in particular settings. It may be most feasible to apply conditions if sale is largely though primary health care settings, including pharmacies, and community-based organisations which are members of national peak bodies representing priority populations for HIV. National peak bodies representing priority populations for HIV include NAPWA (National Association of People with HIV Australia), AFAO (Australian Federation of AIDS Organisations) and Scarlet Alliance. Settings selling self-tests should ensure that staff involved in their sale have completed appropriate training about HIV and self-testing. Ensuring these conditions are met for internet-based sale of HIV self-testing kits is likely to be challenging.

We support the proposed requirement for the sponsor to provide the TGA with regular reports to enable monitoring of test performance. Related conditions should include mechanisms to provide product warning and recall mechanisms.

A comprehensive evaluation of the outcomes of HIV self-testing should be part of the roll-out of this technology, including diagnostic yield, contribution to clinical and public health management of HIV, use of associated support services, and any adverse consequences.

The current Tasmanian *HIV/AIDS Preventive Measures Act 1993* has a range of provisions regarding counselling about and requesting a HIV test, and the processing and managing the information relating to a HIV test. These pose potential challenges to the availability of HIV self-testing kits in Tasmania. However it is anticipated that this legislation will be repealed during 2015, thereby removing this barrier.

The recent experience of the United States and United Kingdom will be useful to consider, to understand the value and pitfalls of HIV self-testing, but with an Australian perspective in mind. The overall usefulness of HIV self-testing will ultimately depend upon the extent to which it can meet needs that are not currently met by existing testing, while any associated public health risks are mitigated.

Yours sincerely

[redacted]

Dr Mark Veitch
A/Director Public Health

30 January 2015