Government of **Western Australia**
Department of **Health**
Public Health and Clinical Services
Communicable Disease Control Directorate

Dr Anthony Hobbs
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Dear Dr Hobbs

CONSULTATION: PROPOSED PERFORMANCE REQUIREMENTS FOR TESTS TO DETECT THE PRESENCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Thank you for the opportunity to respond the Therapeutic Goods Administration consultation on the proposed performance expectations and risk mitigation strategies for HIV point-of-care and self-tests.

The response on behalf of the Western Australian Department of Health is attached for your consideration.

Yours sincerely

[redacted]

Dr Paul Effler
ACTING DIRECTOR
COMMUNICABLE DISEASE CONTROL DIRECTORATE

28 January 2015

Att.

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WA HEALTH - RESPONSE TO THE THERAPEUTIC GOODS ADMINISTRATION (TGA) CONSULTATION ON PROPOSED PERFORMANCE REQUIREMENTS FOR TESTS TO DETECT THE PRESENCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN AUSTRALIA

The Western Australian Department of Health (WA Health) supports the need to establish performance requirements for all forms of HIV testing.

WA Health agrees that 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. Where the benefits outweigh the risks, WA Health 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 and other languages commonly spoken in WA.

The number of HIV notifications in WA is increasing and there may be a significant proportion of people infected with HIV who are undiagnosed and do not know they are infected. Despite the introduction of new clinical models providing HIV and STI testing, the 2014 Perth Gay Community Periodic Survey shows that only 65.8% of HIV-negative gay men reported 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.

HIV self-tests

By its very nature, self-testing does not involve interaction with a practitioner who can outline the limitations, appropriateness and implications of the test. Therefore, strategies are required to address this deficit. WA Health acknowledges that a number of mitigation strategies have already been included in the TGA document and suggests that:

- Consideration must be given to how online and 24-hour phone support can be provided. WA Health currently supports a 24-hour Health Direct phone line and a 24-hour PEP line (for non-occupational post-exposure prophylaxis) which are staffed by suitably trained health professionals.
- Support via telephone and /or online must promote the need for sexually transmitted infection (STI) and other blood-borne virus (BBV) screening, in addition to HIV testing.
- Print information provided with self-testing kits should inform users about the additional need for STI and other BBV screening if they have engaged in practices that have put them at risk for STIs as well as HIV. As outlined in the TGA document, information must also clearly inform users that the test is only a screening test and is not definitive. There must be clear explanations about the reduced sensitivity of the test (in a self-testing environment), the implications of the window period and of a negative result shortly after a high risk event.
- Consideration must be given to providing the same information in multi-language formats.

- Consideration needs to be given to training of point-of-sale healthcare providers, e.g. pharmacists/pharmacy assistants selling self-testing kits will require training to support clients at the point-of-sale in relation to the test limitations, onward advice for clients if tests do not work etc. This could be similar to the model used for sale of fit-packs in the Needle and Syringe Program training for pharmacies.

In reviewing the operational criteria for HIV self-tests the proposed performance requirements for sensitivity and specificity would exclude the only FDA approved self-test (OraQuick In-Home HIV). Will the OraQuick In-Home HIV test be approved for use in Australia? What alternative tests are to be considered by the TGA for home/self-testing?

It is important to ensure that meaningful evaluation of self-testing is undertaken. Suggesting the sponsor will report on false negatives and false positives implies some active surveillance program. This would require thorough consideration and consultation with jurisdictions.

Point-of-care testing

Regarding conditions of approval placed on point-of-care testing (PoCT), WA Health notes the concern expressed about the placement of strict conditions on HIV PoCTs and the impact on the uptake of PoCT. However, it feels that the specific conditions placed upon products in order to ensure quality of the product and testing procedures are reasonable.

WA Health supports the inclusion of appropriately trained staff working under the supervision of a health care professional (e.g. medical practitioners, registered nurses) being allowed to provide PoCT.