

Dr Anthony Hobbs  
Principal Medical Advisor  
Therapeutic Goods Administration (TGA) Executive  
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Dear Dr Hobbs,

Thank you for the opportunity to comment on the Therapeutic Goods Administration TGA consultation paper *Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests* (Version 1.0, November 2014). This submission has been provided by the HIV Foundation Queensland, in consultation with Queensland Positive People.

The HIV Foundation Queensland (HIVFQ) and Queensland Positive People (QPP) strongly support expanding overall access to HIV testing in Australia as a crucial strategy for working towards the virtual elimination of new Australian HIV transmissions by the end of 2020 (Council of Australian Governments Health Council AIDS 2014 Legacy Statement). Further, we support HIV testing performed at the point of care, and in a self-testing environment as they have been shown to increase earlier detection and enable earlier treatment leading to improved individual health outcomes and a reduction in ongoing HIV transmission.

As requested comments address the performance requirements, risk mitigation strategies and conditions of approval in relation to HIV laboratory, point of care tests (POCT) and self-tests.

### **Laboratory tests**

No comment

### **HIV Point of Care Tests (POCT)**

#### Performance requirements

HIVFQ and QPP broadly support the sensitivity and specificity requirements as a presumptive screening tool with the following comments:

- The studies to be provided by manufacturers to demonstrate the performance of the test needs further clarification.
- It should be stated if the studies on sensitivity and specificity are based on samples tested outside the window period as the test is not designed to detect people inside the window period.
- It should be stated if the required studies will define the window period of the particular test or if a window period for all rapid tests be applied.

- Do these studies need to be Australian specific or can they be comparable settings and populations?

#### Risk mitigation strategies

HIVFQ and QPP broadly support the risk mitigation strategies.

#### Conditions of approval

HIVFQ and QPP broadly support the conditions of approval with the following comments:

- The consultation paper states “Specified health care professionals or appropriately trained staff under the supervision of a health care professional”. We would like to recommend clarification of the term “supervision”.
- We strongly support utilising peer educators to perform POCT. We recommend that the scope of *supervision* to be included in the Conditions of Approval is to provide clinical oversight to ensure all operators are correctly performing all aspects of the testing process. This may include off-site supervision with the agreement of the supervisor and appropriately trained staff.
- RAPID is a trial peer led HIV POCT service in Brisbane, Queensland. It has been operating very successfully since August 2014 with 432 tests being performed including seven (7) reactive tests. 57 of the 432 tests performed (13.2%) have been performed on men who have sex with men who have never been tested. 99% of clients were satisfied with their testing experience and 94% of clients would test more frequently at a peer-based service, like Rapid. The trial is expanding to include outreach venues. Off-site supervision has been utilised under these trial conditions with no negative issues arising in the last six (6) months. Feedback from clients using this peer led testing service is that high risk gay men and other men who have sex with men prefer to access testing in a non-healthcare setting.
- Restrictions on *supervision* will significantly curb the ability of community based and peer led HIV testing services to be able to offer much needed and valued out of hours provision. Allowing for a less restrictive definition of supervision would enable the provision of HIV testing to expand in a greater variety of settings by a greater variety of trained personnel. Health care professionals may at times require additional support but there is no requirement that there is another health care professional on site for them. It appears inconsistent that appropriately trained staff, who have been assessed as competent to perform HIV POCT to the required standard are not subject to the same conditions.
- We support the provision of HIV POCT in a variety of community based settings. We recommend that the scope of location/environment include an environment where the individual can be provided with appropriate counselling and follow-up testing and referral pathways for support and treatment if required.

### **HIV Self-Tests**

#### Performance requirements

HIVFQ and QPP broadly support the reduced sensitivity and specificity requirements based on user inexperience and acknowledgement that self-tests are a presumptive screening tool.

### Risk mitigation strategies

HIVFQ and QPP broadly support the risk mitigation strategies with the following comments:

- We would like to recommend that the wording is amended from "the need to consult a medical practitioner for confirmatory testing of positive results by a laboratory test" to "confirmatory testing of *reactive* results" to acknowledge that self-testing is a screening rather than diagnostic test.
- How to contact support and counselling services needs to be localised or include local contacts for all Australian jurisdictions.

### Conditions of approval

HIVFQ and QPP broadly support the conditions of approval. Other conditions of approval could relate to restriction of where the tests could be sold with additional consideration given to organisations with peer educators acting as a point of sale for HIV self-tests.

Thank you again for the opportunity to provide comment on the consultation paper. We look forward to hearing of the outcomes.

Yours sincerely



HIV Foundation Queensland