Submission to:

Therapeutic Goods Administration: *Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests Version 1.0 November 2014*

January 2015

About ACON

ACON is New South Wales' leading health promotion organisation specialising in HIV. 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. Additionally, ACON runs a number of HIV and STI screening services across NSW.

Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests

An increased rate and frequency of voluntary HIV testing is required to work towards the virtual elimination of HIV, a goal of both the *NSW HIV Strategy 2012-15* (the NSW Strategy) and the *Seventh National HIV Strategy 2014-2017* (the National Strategy). Increased rates of voluntary testing are set as targets in both strategies. Increased voluntary testing is important to achieving other targets of the NSW Strategy and the National Strategy, including increasing rates of treatment amongst people living with HIV (PLHIV), and making informed decisions about safe sex.

Since the limited introduction of HIV point of care testing (PoCT) in NSW there has been an increase in the number of HIV tests performed across the state. This increase has been seen in the general community and amongst gay and other homosexually active men (GHAM), a priority population in both the NSW and National Strategies. These increases have followed a period of stability in testing rates amongst GHAM prior to the introduction of PoCT. This increase in testing was expected as PoCT addresses a number of barriers to traditional forms of testing that researchers have identified. We believe that we will see a similar effect once high quality HIV self-testing (HST) devices are made available in Australia.

We have limited our comments in this submission to the performance requirements and risk mitigation strategies related to PoCT and HST.

Working in partnership has been an important feature of the response to HIV in NSW. As such we have seen drafts from the Australian Federation of AIDS Organisations (AFAO), the NSW Ministry of Health and the Kirby Institute and we endorse their submissions.

Performance Requirements

We agree that a stratified model of performance requirements across different types of HIV testing devices is required. We believe that screening devices should not be assessed on the same basis as diagnostic tests, such as HIV nucleic acid tests. This would be an inappropriate standard against which to assess PoCT and HST devices as these devices are intended to lower the barrier to testing, and to engage more people in regular testing.

We note that the Review of Medicines and Medical Devices Regulation is currently underway. In the discussion paper produced by the review, there was a suggestion that the TGA could accept decisions made by trusted overseas regulators. We support this direction and believe this could make the approval process more streamlined, enabling the TGA to focus on local risk mitigation strategies for the use of those devices.

PoCT

We support the inclusion of a public health perspective in the assessment of PoCT devices. The discussion paper acknowledges that "rapid HIV diagnostic testing in the point-of-care setting is an important strategy to expand access to HIV testing". We agree with the statement, but believe that this should read "rapid HIV testing in the point-of-care".

We also support the differential performance requirement between whole blood and oral fluid tests. We believe that this is an appropriate recognition of the importance of lowering the threshold to HIV testing for people and increasing regular HIV testing amongst GHAM.

We defer technical discussions of performance of PoCT to the Kirby Institute, who we understand are making a submission to this consultation.

HST

We welcome the recognition that the performance of HST devices should primarily be judged on performance in controlled laboratory settings, and that useability in the hand of a consumer should not be expected to be the same as when used by an appropriately trained person.

Risk mitigation strategies

PoCT

In the introduction to the mitigation strategies section on PoCT there is a reference to 'pre- and post-test counselling'. The current practice for undertaking HIV testing, as outlined in the *National HIV Testing Policy*, in any professional setting is that informed consent is gained, rather than pre- and post-test counselling and this should be reflected.

We agree that discussion of the window period and the time between any risk event and testing is important, and that this information on the window period needs to be included on the instructions for use (IFU). We would like to see the list of risk mitigation strategies related to the window period of a test expanded to include parallel laboratory testing, and referral to laboratory testing once the window period for laboratory tests has been reached.

This section of the paper also refers to the National Pathology Accreditation Advisory Committee's *Guidelines for Point of Care Testing*. We have not seen a recent version of these guidelines, and as such cannot endorse them. Instead we would suggest removing this reference, or that state based guidelines should be listed as well. We have worked in partnership with the NSW Ministry of Health to develop the NSW Framework and Standard Operating Procedures for HIV Point of Care Testing. The HIV testing services that ACON operate are undertaken within these guidelines and from experience we believe them to be appropriate guidelines for PoCT.

HST

As noted in our discussion of PoCT above, the discussion of risks associated with HST should refer to *informed consent* rather than *pre- and post-test counselling*.

When advocating for the availability of HST, ACON has called for comprehensive IFU to be included with an HST device. The IFU must include information about the use of the device, interpretation of results and linkage to care. We agree that information about high risk behaviour and safety is essential, though we caution that any discussion must have a contemporary understanding of what constitutes safe sex.

Another of the risk mitigation strategies is to provide online or telephone support services for users of HST. We note that the NSW Ministry of Health has, in their submission to this consultation, said that *healthdirect* and *NSW Sexual Health Infolink* are appropriate information lines for people using HST devices. We think this is a sensible proposal and support this as an appropriate response to the need for telephone support. Specialist HIV services such as the Post Exposure Prophylaxis (PEP) infolines in each state should also be investigated as possible sources of support.

We have concerns about the language used when talking about the requirements placed on manufacturers/sponsors in the last paragraph of the HST section. We believe that it would be impossible for a manufacturer or sponsor to "demonstrate that any benefits gained from use of the test (i.e. increased testing rates) would outweigh any risks associated with the use of the product (i.e. false negatives)". It would be impossible to demonstrate how any individual tests would have an impact on testing rates. We expect that they will collectively have an impact, and while it may be possible for this to be projected, it could not be demonstrated until after the introduction of the device.

Conditions of approval

For both PoCT and HST devices we want to ensure that any conditions placed on devices at the point of approval should not limit the availability of a wide range of quality devices. It is acknowledged throughout the proposal that there are benefits to be gained from increased numbers of people testing, and increased frequency of HIV testing among priority populations. This increased access should not be undermined by onerous conditions.

PoCT should be able to be administered by appropriately trained persons. This is important, as it allows peers to undertake testing. Peers undertaking testing has been important to the success of ACON's a[TEST] service, a rapid HIV and STI testing service.

The supervision condition attached to the approval of the Alere Determine HIV ½ Ag/Ab Combo (Alere Determine) device is unclear and problematic. ACON had developed a peer based testing service in partnership with Sydney Sexual Health Clinic as part of a study undertaken with the Kirby Institute. Before the end of the study, ACON had to plan how to transition our service from using a different device, Trinity Unigold, under study conditions. Our model has been shown to be successful, both in terms of client satisfaction and in terms of reaching people who had never tested for HIV.

Initially this supervision condition attached to Alere Determine appeared to prohibit the ongoing operation of a[TEST] in its existing format. After clarification from the TGA it was apparent that this condition was not a problem for our service.

However, we believe this condition should be removed from the approval of Alere Determine and not attached to other devices. Existing conditions including having a quality assurance programs in place, a link to a National Association of Testing Authorities and appropriate training are strong enough to ensure that the devices are used in appropriate settings by appropriately trained staff.

Conclusion

We thank you for the efforts that have been put into this review and the openness to reform that the TGA has shown. We believe that the outcome of this review needs to be linked into the Expert Review of Medicines and Medical Devices Regulation in Australia. We hope that the outcomes of both of these consultations will ensure timely access to a wider range of testing options and biomedical prevention tools, assisting in the fight to end HIV.