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Dear Therapeutic Goods Administration,

Performance Requirements for HIV Tests

Thank you for your invitation to consult on the proposed performance requirements for tests to detect the presence of HIV.

As you appreciate, the development of HIV technologies continues to impact upon sex workers in Australia and we are pleased to contribute to this consultation.

Sex workers in Australia require easy access to safe, voluntary, free, anonymous, confidential HIV testing without fear of criminalisation and associated consequences. Although a low-prevalence population for HIV, sex workers remain an over-tested population, with legal and policy barriers to accessing safe testing.

Scarlet Alliance welcomes the development of strategies to mitigate risk associated with new forms of HIV testing (in particular, point of care testing and self-testing) and submits that these strategies must address (and reduce) the risks associated with the legal and policy environment in which these tests will be conducted.

We have provided the TGA previously with information on mandatory HIV testing of sex workers and criminalisation of sex workers living with HIV in various jurisdictions in Australia (see submission on home testing, 6 May 2014). These laws continue to affect the ways in which sex workers can interact with new HIV technologies, and the implications these technologies will have on sex workers lives, careers and privacies.

To be accepted for inclusion in the Australian Registrar of Therapeutic Goods, all tests must demonstrate that they do not compromise health and safety. Potential uses of point of care testing (for example, in sex work workplaces or as part of mandatory testing of sex workers) compromise sex worker health and safety.

We agree that different modes of testing, test administrators and testing environments bring different risks and require different risk mitigation strategies, and submit that these risks also differ between populations and jurisdictions. Risk mitigation strategies must be relevant to the populations who will be using these tests and the environments in which they will undertake them. Risk mitigation includes not only informing consumers of risks but also placing conditions on manufacturers and sponsors in terms of how and where testing can be conducted, to minimise the risks posed by the legal framework and ensure HIV testing is happening in a manner consistent with Australia's national HIV Strategy, HIV Testing Policy and our international human rights obligations.

The proposed requirements

Scarlet Alliance accepts broadly the aim of finding a balance between the need for high quality tests that are fit for purpose and improving access to HIV testing, via performance requirements and risk management strategies.

We accept broadly the stratified model summarised in Table 1 combined with performance requirements and risk mitigation strategies (including conditions of approval) however we make additional recommendations and qualifications below.

We accept that a HIV Point of Care Test and self-tests may be considered fit for purpose at a lower level of sensitivity and specificity if the risks associated are mitigated and the benefits outweigh the risks. We agree that all tests for HIV should demonstrate the highest possible standard of performance relative to the intended purpose.

Suitability and effectiveness of the proposed risk mitigation strategies

Point of Care Testing

It is important to acknowledge that different communities will experience different levels of risk. The risks for sex workers go beyond those listed in the proposal. Criminalisation and mandatory testing compound the risks of false positives for sex workers. Clinical trials on the risks and efficacy of these tests among gay men generally, are not transferrable to sex workers, including gay male sex workers. Low rates of STIs and HIV and high rates of condom use are not limited to certain sub-populations of sex workers. The Law and Sex Worker Health study by the Kirby Institute states that condom use amongst male sex workers is high.[1]

We agree with the proposed mitigation strategies that require the test to be easy to perform with clear instructions for use and clearly identified limits, including sensitivity, specificity, window periods and confirmatory testing. The instructions for use should be clearly accessible on the packaging, as well as made available to the TGA. Manufacturers should commit to actively working to improve the test in response to emerging data about its use in diverse populations.

For Point of Care tests, it is important to ensure that the consumer and test administrator understand that the test is intended for presumptive screening of HIV rather than diagnosis – this should be included in the instructions for use.

We further submit that the instructions for use should include a clear statement that Point of Care testing is not recommended for use in populations with low prevalence of HIV. Both the National HIV Strategy and National HIV Testing Policy reiterate that Point of Care testing is intended for high prevalence populations only. This is crucial to iterate because, as a low prevalence but over-tested population, the chance of a false positive from rapid testing is higher for sex workers than for other population groups.

The Kirby Institute examined more closely what it means when rapid tests are used in low prevalence populations. Their research compared rapid testing data for MSM populations with rapid testing data for female sex worker populations. Using a specificity of 99.4%, which was the observed specificity using Alere Determine in an Australian Study by Dr Damian Conway and colleagues, the calculations found that this test used in a high HIV prevalence population, such as MSM testing at sexual health clinics in Australia, would produce 1 false positive for every 2.3 true positives (6 false positives for every 14 true positives). The same test if used in a low prevalence population, such as female sex workers tested at sexual health clinics in Australia, would produce many more false positives than true positives; there would be 15 false positives for every one true positive result.[2] This is an extraordinary difference.

[1] Basil Donovan, Christine Harcourt, Sandra Egger and Christopher Fairley, 'Improving the health of sex workers in NSW: Maintaining Success', *Public Health Bulletin,* 21 (3-4), 2010, 74 at 76.

[2] P Keen, Kirby Institute, 2014. Overall specificity of the TGA-licensed Determine HIV-1/2 Ag/Ab Combo rapid HIV test, as observed in an Australian study of MSM: Conway, D., Holt, M., McNulty, A., Couldwell, D., Smith, D., Davies, S, Cunningham, P, Keen, P, Guy, R. (2013); *Field performance of the Alere Determine HIV Combo assay in a large Australian multicentre study in a sexual health clinic setting.* STI & AIDS World Congress 2013, Vienna; The Kirby Institute. HIV, viral hepatitis and sexually

The instructions for use should also state that Point of Care testing should not be used in workplaces or as part of mandatory testing, and that health professionals should not take on a law enforcement role. Sex workers already have sexual health services arriving in their workplace during working hours because sexual health workers believe testing in those environments are 'more convenient' for sex workers. Point of Care tests pose unique issues because the results are available within 30 minutes. Workers would receive results during their shift, whilst sharing space with peers, clients and employers – the likelihood that the right to privacy could be maintained in this setting is low.

Unlike the concerns already identified in the report that restrictions will hamper the uptake of testing, the danger for sex workers is over-testing in criminalised environments that do not have our safety at heart and by health professionals with less safeguards for our confidentiality.

Sex workers should have choice. Where Point of Care Tests are offered they should always be offered in parallel with conventional testing. This should be explicit in the instructions for use. Rapid tests are only one testing option and do not replace conventional STI/HIV testing: testing efficacy is important for sex workers as we negotiate and manage risk. Where a client presents for a test within twelve weeks of a high-risk event, they should be offered a conventional (laboratory venous blood draw) HIV test or referred for a conventional test elsewhere, instead of a rapid test. This should form part of the pre-test discussion.

The instructions for use should therefore state that anyone administering a Point of Care test must also comply with the National HIV Testing Policy, which provides that testing is conducted ethically and is beneficial to the person being tested.

The instructions for use should further state that negative results obtained within three months of a high risk event should be repeated at three months to confirm the initial negative result, as false negatives can be obtained if testing is performed during the window period. The window period should be defined in the product information.

HIV Self-tests

Scarlet Alliance supports that self-tests must be straight-forward to use in a home-testing environment with minimal steps and clear and simple instructions on performance and interpretation of the test.

Issues arise with self-testing around how tests will be available and used. Although sometimes referred to as 'home testing' there are no assurances that these tests will only be used in the privacy of one's home or that as 'self-testing' the tests will not become part of a negotiation of safer sex services where someone is given a test by another and expected or pressured to use it in their company. There should be a minimum window period requirement for self-tests set out in the guidelines for manufacturers.

Our concern is that once that test has been purchased (whether by prescription, vending machine or at a supermarket), there is no way of enforcing how that test will be used by an individual and that it will not be presented to another person who is then pressured to test. For sex workers, the risk is that this pressure occurs in a work environment or work interaction – as part of mandatory testing regimes or clients presenting with self-tests requesting unprotected services.

There is a real risk that sex industry workplaces (for example, brothels) could require workers to self-administer HIV tests as a condition of employment. This is particularly the case in jurisdictions such as Victoria or Queensland where mandatory testing laws place an onus on business owners to ensure workers undergo testing. Clients could also arrive at a workplace and request a sex worker to undertake a self-test before the booking, or could bring the result of their own test to ask for unprotected services. Sex workers medical privacy and HIV status could be compromised, particularly where a refusal to take a test could be seen as an indication of HIV positive status.

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transmissible infections in Australia Annual Surveillance Report 2013. The Kirby Institute, The University of New South Wales, Sydney NSW 2052.

Reports from sex workers at the Empower Foundation in Thailand state that sex workers are being offered financial incentives (up to a day's wage) to undergo a rapid test. Health care providers may be required to meet certain targets for testing those perceived to be in high risk groups in order to receive funding. Sex workers report sexual health clinic staff arriving spontaneously at their workplace to conduct blood tests on the premises, and those workers who declined testing were treated with suspicion. In Australia, in jurisdictions with mandatory testing in place, sex workers have reported brothel operators requiring them to see a doctor of the operator's choice, following which the results are handed directly back to the operator rather than the worker, without regard for that worker's right to privacy.

These risks are compounded in states and territories in which working as a sex worker living with HIV is criminalised. Where this is the case, self testing with rapid tests would mean that sex workers are potentially criminalised upon receiving a positive or 'reactive' result. The process of waiting for confirmatory testing, especially if the test is administered in a workplace environment around peers raises issues around the person's legal work status, confidentiality, prosecution, discrimination and stigma. A reactive or indeterminate result will immediately place a person's occupation, career and income at stake. This is regardless of whether individual workers practice safer sex, cater to specifically HIV positive clients, or offer non-penetrative services. This risk is compounded because sex workers as a 'low prevalence' population are more likely to receive false reactive results.

The instructions for use should clearly state that self-tests should be voluntary, and that a person cannot be required to self-test under the instruction or direction of another person. They should state that self-tests should not be used in workplaces or as part of mandatory testing.

The manufacturer/sponsor of an HIV self-test should clearly outline on the instructions for use the limitations of the test (including specificity, sensitivity, window periods and risks of false positives and negatives) – this should be in plain English and translated into key community languages in the area of distribution (for Australia, into Thai, Korean and simplified Chinese at minimum).

There should also be an obligation on manufacturers/sponsors to provide the TGA with regular reports on the numbers of false positive/negatives and problems with the test, and make this available on their website, with a link on the packaging.

The instructions for use should contain information about the risk of false positives in low prevalence populations (not only the risk of false negatives). It should reiterate that self-tests are not recommended for low prevalence populations.

There is also a risk that a focus on HIV testing will de-link comprehensive sexual health testing. Currently HIV tests in clinical and community settings include STI screenings, allowing for a more comprehensive health assessment. The instructions for use should recommend users seek comprehensive STI testing.

Sex workers require specific supports in the case of a reactive result to a self-test. Sex workers need information and access about their local sex worker organisation, the legal framework they operate under, and where to find targeted peer support.

The instructions for use should also provide a 24-hr phone line and online support for users, in addition to a list of appropriate counseling and referral services, including LGBTIQ and sex worker friendly counseling services and peer organisations.

It is important to ensure that consumers understand that self-tests are intended for presumptive screening of HIV rather than diagnosis – this should be included in the instructions for use.

Conditions of approval

Scarlet Alliance has reviewed the summary of current product specific conditions for a HIV PoCT Registered in the Australian Register of Therapeutic Goods.

We submit that in addition to Point 2, where the sponsor of the device must make available training in the correct use of device and interpretation of results, this training must include familiarity with the

principles of the National HIV Testing Policy. In particular, training must ensure health professionals understand that Point of Care Tests are not targeted towards low prevalence populations, should not be used as part of mandatory or workplace testing, and should not be combined with contact tracing. (Contact tracing has resulted in sex workers living with HIV being publicly vilified and their privacy and confidentiality breached). Voluntary, confidential, anonymous, free and patient-initiated testing remains the best-practice approach to STI and HIV testing.

Conclusion

Scarlet Alliance submits that a number of conditions be placed on the supply and use of HIV self-testing devices to manage risks associated with their use. These risk management strategies must be in place as a matter of priority. They should be included explicitly in product information, on the manufacturers website, within package inserts and other promotional material.

Some of these points may seem self-evident. Of course testing should always be voluntary, and the tests are designed for an individual to test themselves rather than require a sexual partner or colleague to test in their presence. However, in the current sex work legal and policy environment, these conditions must be spelt out. If they are not spelt out clearly and comprehensively, it will be sex workers and sex worker health that will bear the cost. It is sex workers who will face an increasingly coercive testing environment. It is sex workers who are already over-tested and face risks of imprisonment and loss of privacy, job and livelihood.

We understand our feedback will be used to develop comprehensive guidance to industry for developing applications to the Australian Register of Therapeutic Goods, to establish performance benchmarks for the TGA in evaluating HIV tests for safety and performance, and to assist in developing conditions placed on the supply of a device to assist in risk mitigation.

Please do not hesitate to call our office on (02) 9690 0551 to speak with our Chief Executive Officer [redacted] should you wish to discuss this submission further.

Kind regards,

[redacted]

Ryan Cole
President