napwha national association of people with HIV australia

Submission to TGA

Consultation on Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests

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The role of NAPWHA

Founded in 1989, the National Association of People with HIV Australia (NAPWHA) is the peak organisation representing people with HIV at the national level. Our members comprise State and Territory organisations of people living with HIV.

NAPWHA promotes the meaningful involvement, visibility and centrality of people living with HIV in all aspects of Australia's HIV response. Our focus is on policy and program advocacy to help ensure that Australia attains the highest standards in HIV prevention, treatment, care and research.

NAPWHA's Involvement in Regulatory Issues

NAPWHA and our members are strong advocates for the meaningful involvement of consumers in regulatory and funding processes for medicines and medical devices.

The operation of the TGA and the PBS are priority areas of interest for NAPWHA. We have a long history of involvement in regulatory issues concerning medicines, medical devices, clinical trials and scientific research. We work closely with clinicians, researchers and the pharmaceutical industry to ensure prompt access to clinical trials and new medicines and devices to treat and prevent HIV. This work often includes interaction with Australia's prescription medicine and medical devices regulatory and funding processes.

NAPWHA's Overall Position on the Medical Devices Regulatory System and the Regulation of HIV Tests

There are a range of devices to prevent, screen, diagnose and monitor HIV infection that play an essential part of Australia's HIV response. The effectiveness of the system for regulating these devices is therefore an important focus for NAPWHA and other organisations involved in HIV. This is particularly the case for new devices which are innovative in design or performance and can assist the uptake of HIV prevention, testing and treatment.

Stakeholders in the HIV community sector are frustrated by regulatory decision making processes and by the long timelines to consider applications for registration of some HIV tests. Also, sufficient weight does not seem to be given to the public health imperatives associated with access to these tests.

Some recent examples include:

- Long assessment timelines and ultimate rejection of licensing of the [redacted] based on a TGA performance criterion that is arguably impractical and unattainable.
- Long assessment delays and rejection of the [redacted] for similar reasons as above.
- Long delays (2016 and beyond) before the TGA is likely to consider and approve HIV self-testing kits, which are an important new technology for supporting HIV prevention. [Note: the Orasure HIV self-test was US FDA approved in 2012 and is widely available in the US. However, it is unlikely to be registered in Australia until 2016.]

NAPWHA therefore welcomes this TGA consultation and hopes that it will result in early action to improve access to and uptake of HIV testing in Australia. However, this consultation and our response to it should be seen in the context of the wider *Review of Medicines and Medical Devices*

Regulation[1] (the Sansom Review), which is now in progress and to which we have made a detailed submission. Our submission to the Sansom Review calls for substantial changes to Australia's regulatory system for medicines and medical devices to address areas of unnecessary, duplicative and ineffective regulation.

Accordingly, NAPWHA considers that changes that may result from this TGA HIV testing review may need to be reconsidered in terms of wider reform of the regulatory system that may arise from the Sansom Review.

NAPWHA's Responses to the Specific Questions in the TGA Consultation Paper

1. Performance requirements: whether or not you support the proposed requirements. If you do not support the proposed requirements you may make suggestions for alternative requirements that are acceptable to you and supporting reasons.

NAPWHA supports most aspects of the proposed performance requirements detailed in the text and in Table 1 of the TGA's *Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests (Nov 2014).* However, we make the following points in relation to these proposed requirements:

- The principle of alignment with EU and FDA standards and performance criteria should be applied wherever possible to avoid duplication of effort in TGA regulatory consideration of new HIV tests.
- The stratified operational procedure criteria (p13) for the detection of HIV antibodies in relation to HIV self-tests needs clarification: the proposed wording mentions requiring *"additional usability studies to demonstrate the effectiveness of the test in inexperienced hands."* Other than in exceptional circumstances, NAPWHA does not support additional studies being required by the TGA to those already considered by credible overseas regulators (EU and FDA for example) in their regulatory decision making for HIV tests. Requiring additional studies will likely result in delays in approving new HIV tests.
- The *NSW Framework and Standard Operating Procedures for HIV Point of Care Testing (2014, NSW Ministry of Health)* should be considered for use by Australian jurisdictions who have not yet developed guidance for delivery of HIV testing in clinical and non-clinical settings.

2. Risk mitigation strategies: an assessment of the suitability and likely effectiveness of the proposed risk mitigation strategies to be employed by manufacturers to allow a risk/benefit assessment of a device. If you do not support the proposed risk mitigation strategies you may make suggests for amendments to the proposed strategies or suggestions of additional risk mitigation measures.

NAPWHA supports most aspects of the risk mitigation strategies proposed in the TGA's *Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests (Nov 2014).* However, we make the following points in relation to these strategies:

- Clarification is needed on the question of who should be approved to administer PoCT HIV tests. NAPWHA considers that appropriately trained personnel from community based

[1] Review of Medicines and Medical Devices Regulation, Sansom L, Commonwealth Department of Health 2015.

organisations should be able to administer, interpret and provide results for PoCT HIV tests, in addition to trained registered nurses and doctors.

- NAPWHA agrees that clinical oversight of PoCT HIV testing is necessary, but that this should not necessarily require the onsite presence of registered nurses or doctors: instead, protocols and procedures should be in place so that immediate reference to advice from nurses or doctors is available in situations where questions or difficulties arise.

3. Conditions of approval: whether or not you support the proposed conditions of approval. If you do not support the proposed conditions you may make suggestions for alternative conditions that could be considered.

NAPWHA supports most aspects of the conditions of approval proposed in the TGA's *Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests (Nov 2014).* However, we make the following points in relation to these conditions:

- NAPWHA considers that conditions on approval of HIV self-test kits should not be so onerous as to diminish the wide-availability of self-testing.

- Requiring sponsors to provide the TGA with reports of false results or other problems with HIV self-test kits is a sound principle, but may be impractical in some respects because once supplied it is largely up to consumers to report problems with the test kits. This may be a challenge because a significant number of consumers using self-testing may be less-willing to interact with established medical and health services (this may be why they seek to use HIV self-tests in the first place). However, in recognising these limitations, it would be reasonable for HIV self-test manufacturers to report on distribution patterns and on problems reported about the operation of HIV self-tests. This will need to be done in a way that encourages health professionals and consumers to provide feedback but also protects privacy and confidentiality.

- The proposed conditions of approval do not mention the issue of who can provide or sell HIV self-test kits. In order to maximise uptake of HIV testing, NAPWHA expects that self-tests will be available for purchase from pharmacies and from on-line suppliers. There are a range of government and non-government health services and organisations that should also be able to supply HIV self-tests to people unwilling to attend point of care HIV testing services.

- NAPWHA does not believe it is necessary to establish a 24 hour phone line for HIV self-tests. Such a proposal was initially set up in the USA, but has now been abandoned through lack of use. There are a range of emergency health and support telephone lines in Australia which can deal with issues concerning HIV self-testing (e.g. healthdirect). An online video to assist consumers should be available. Community based HIV organisations will be able to assist with inquiries concerning HIV self-testing.

30 January 2015