

Dr Anthony Hobbs
Principal Medical Adviser
Therapeutic Goods Administration
PO Box 100 Woden ACT 2606

Dear Dr Hobbs,

Thank you for the opportunity to provide input into TGA's consultation regarding Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests.

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters and suppliers of medical technology products in Australia, including medical devices and in vitro diagnostics (IVDs).

MTAA represents companies which account for the majority of products included in the Australian Register of Therapeutic Goods (ARTG), and approximately 75% of implantable medical devices listed on the Prostheses List used in the Australian market.

MTAA member companies cover the full spectrum of the industry in Australia; from subsidiaries of major multinational medical technology companies, to independent distributors and small-to-medium sized Australian innovator companies.

MTAA wishes to provide the following comments regarding the proposed performance requirements and benefits associated with HIV self-test IVDs.

1. Performance requirements for HIV home-use kits

The acceptable performance criteria for HIV self tests are proposed to be:

Same performance requirements as HIV point-of-care tests (PoCT) when used in controlled laboratory conditions with additional usability studies to demonstrate the effectiveness of the test in inexperienced hands, including:

- *Effective sensitivity (in the hands of inexperienced user)*
- *low inter-reader variability*
- *invalid/error rate of <2%.*

MTAA suggests that the proposed performance for HIV self-tests would appear to be unrealistic. The 'effective' sensitivity and specificity of the test (i.e. in a self-testing environment) should be set lower than laboratory based testing.

Availability of HIV home-use test is intended to increase HIV testing (and frequency of testing) and is not intended to replace the laboratory ELISA-based testing – currently the "gold standard" testing method for HIV. Further, TGA approved laboratory nucleic acid amplification techniques (NAT) testing performance is reported to be lower than ELISA-based testing, particularly NAT testing pools (≥ 50 RNA copies per ml achieved $\geq 92\%$ sensitivity^[1]).

[1] Gomez LP, Balangero MC, Castro G, Kademian S, Mangeaud A, Barbas MG, Cudolá A, de León JF, Carrizo H, Gallego SV. [Sensitivity of the COBAS AmpliScreen™ HIV-1 test v1.5 for HIV-1 detection]. Rev Argent Microbiol. 2014;46(3):196-200.

2. Benefits of HIV self-testing kits

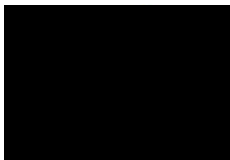
MTAA believes that the benefits of HIV self-testing kits for use in Australia outweighs the limitations of the home-use kits.

Benefits include:

- Ease of use
- Same window period as lab based tests
- Improve the diagnosis of HIV, particularly in men who engage in male-to-male sex – with evidence showing that this group of men are not testing for HIV as often as is recommended and a significant proportion of men remain undiagnosed or diagnosed late. Home testing also may enable men to test more frequently for HIV leading to diagnosis of HIV at an earlier stage. Early detection of HIV can be beneficial in terms of timely entry into care and treatment.
- Reduce sexual HIV transmission. Early detection and treatment can substantially lower the risk of transmission to sexual partners - reduce the risk of passing on HIV to a regular sexual partner.^[2]

Without access to home self-test kits, individuals may resort to buying self-testing kits from overseas (online) for personal use in Australia. This may result in individuals choosing unsafe self-testing kit (i.e. kits may vary substantially in terms of quality and accuracy – performance of the test may not be clinically proven to detect HIV and provide inaccurate results, or affected if not handled in accordance to manufacturer's instructions).

Regards,



Susi Tegen
Chief Executive
Medical Technology Association of Australia

[2] Del Romero J, Rio I, Castilla J, Baza B, Paredes V, Vera M, Rodríguez C. Absence of transmission from HIV-infected individuals with HAART to their heterosexual serodiscordant partners. *Enferm Infecc Microbiol Clin*. 2014 Dec 30. pii: S0213-005X(14)00373-5. doi: 10.1016/j.eimc.2014.10.020. [Epub ahead of print].