



Medical Technology
ASSOCIATION OF AUSTRALIA

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Lisa Studdert
Head, Market Authorisation Group
Therapeutic Goods Administration
[REDACTED]

www.mtaa.org.au

Level 12, 54 Miller St, North Sydney
NSW 2060 Australia
PO Box 2016 North Sydney
NSW 2059 Australia
P (+612) 9900 0650
F (+612) 9900 0655
E reception@mtaa.org.au

Dear Lisa, *Lisa*.

Thank you for the opportunity to provide input into the proposal to allow the supply of in vitro diagnostic devices (IVDs) for self-testing for the presence of HIV in Australia.

The MTAAs is supportive of making this type of new medical technology available to all Australians.

Tests for serious diseases (such as HIV) that are safe and reliable should be made available to those most vulnerable in our community, particularly where such tests have been shown to improve rates of diagnosis, and therefore prevent the spread of such diseases in the wider population.

Regulating such tests in the same way as other medical devices allows their supply to be more appropriately monitored, and would help reduce the number of patients seeking to import potentially inferior and unsafe product directly for their own personal use.

The effectiveness of 'home use' IVDs such as this relies on the additional support provided by trained and qualified healthcare professionals, and this support is much more likely to be available to the patient if they are using tests that are being appropriately regulated, as opposed to sourcing product of unknown quality directly from the internet.

Given that individuals are already accessing home use HIV tests through personal importation mechanisms, there would appear to be no additional risk posed by allowing the TGA to approve such products for supply through entry in the ARTG.

Kind regards,

[Signature]
Susi Tegen
Chief Executive