

Tuesday 6<sup>th</sup> May 2014

Lisa Studdert,  
Head Market Authorisation Group  
Therapeutic Goods Administration

Delivered via email to [REDACTED]

**Re: Registration and sale of in-vitro diagnostic devices for self-testing HIV in Australia.**

On behalf of Hepatitis Australia I am responding to the letter sent from Prof. Chris Baggoley and Dr Tony Hobbs sent on the 15<sup>th</sup> April 2014.

Hepatitis Australia fully supports the proposal of the Therapeutic Goods Administration (TGA) for the registration and sale of in-vitro diagnostic devices (IVDs) in Australia for the testing of HIV. Hepatitis Australia's support is based on the premise that such approval can support the community to make a choice to access higher quality devices accompanied by appropriate information, relevant to the Australian context.

While home-testing for HIV is not considered optimal, it is acknowledged that many Australians already purchase such devices via internet based stores in other countries. Providing the opportunity to purchase devices 'approved for use in Australia' would allow higher quality products to be identified, encourage appropriate marketing and support the relevant health organisations to correctly inform the community of their options.

HIV and other blood borne viruses, such as viral hepatitis are notifiable diseases. Current guidelines for testing of HIV or hepatitis C require the patient to be provided with pre and post-test discussion. This model needs to be reinforced in the material provided with or about the IVD products.

Hepatitis Australia suggests that any IVDs approved by the TGA, for use in Australia should be accompanied with appropriate information to:

- Advise of the correct and appropriate use;
- Advise of the reliability and effectiveness of IVDs;
- Strongly recommend medical consultation to confirm the test results;
- Promote safe behaviours; and
- Provide for access to immediate support (eg, national information phone line).

Thank you for this opportunity to discuss this proposal by the TGA and should you wish to discuss the matter further, please do not hesitate to contact our office on 02 6232 4257

Yours sincerely



Helen Tyrrell  
CEO

cc. Julianne Quaine, Office of Health Protection – Dept. of Health