



Ref: 552108

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Chief Medical Officer
Department of Health
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Dr Tony Hobbs
Principal Medical Adviser
Therapeutic Goods Administration
PO Box 100
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Dear Professor Baggoley and Dr Hobbs

Registration and sale of invitro diagnostic devices (IVDs)

Thank you for your letter dated 15 April 2014 regarding the proposal to allow the registration and sale of invitro diagnostic devices (IVDs) for self-testing for the presence of the human immunodeficiency virus (HIV) in Australia.

The Pharmacy Guild of Australia supports the general proposal to allow the registration and sale of these devices for the reasons outlined. However, the Guild believes these products should only be available in community health settings that provide the opportunity for counselling with a health professional, such as a community pharmacist, rather than a purely retail setting or over the internet.

The Guild believes that disease screening and condition management through community pharmacies can facilitate early diagnosis and intervention, enhance the monitoring of chronic conditions, improve therapeutic control and Quality Use of Medicines (QUM), and facilitate greater patient adherence and self-management.

Community pharmacy is Australia's most commonly used primary health care service, with over 400,000 people visiting a pharmacy every day. There are over 5,300 community pharmacies across all regions of Australia, including rural and remote areas.

Community pharmacies with their recognised trust and expertise, close links to local populations and widespread geographical distribution, can potentially provide a high quality, safe and readily accessible location for HIV testing. Community Pharmacy also has experience in providing screening kits and support services for conditions such as bowel cancer, chlamydia as well as needle and syringe programs. This makes community pharmacy an ideal setting in relation to providing safe and effective testing kits to consumers with access to professional advice.

Although the Guild offers in-principle support to this proposal, there are several issues that need be considered prior to approving the sale of these devices in Australia. We believe permitting the use of these testing kits in a community and/or home setting requires a coordinated approach to develop a formal disease screening and condition management professional service for HIV/AIDS. The Guild recommends consideration should be given to:

- Appropriate referral pathways to other health professionals to ensure that the consumer is able to address any results that may be of concern
- The use of data collection and information management software, and the privacy consideration of this data

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- Quality management and standards processes
- The availability of an appropriate consultation/testing area if required
- Adequate training of staff, particularly in the instances of operating Point of Care Testing (PoCT) devices
- Appropriate waste disposal of testing consumables where appropriate
- Infection control procedures if bodily fluids are involved in the testing process, and
- The importance of pre and post-test counselling

In addition, since these products are designed for home testing without health professional oversight, attention also needs to be given to labelling requirements for these products. The Guild believes the product labelling must indicate to patients that these devices may not provide a definitive result due to the nature of the virus and follow-up tests at a sexual health clinic should be strongly encouraged.

Furthermore, a patient discovering they are HIV positive via these devices in their home is likely to be extremely distressed. Therefore we also recommend all HIV testing kits sold in Australia provide the contact numbers for HIV support services and counselling telephone hotlines on their packaging or as an insert so consumers have access to immediate support if required.

Another issue that may warrant consideration in conjunction with this proposal is making HIV treatments such as antiretroviral drugs available through community pharmacy setting.

Thank you for the opportunity to provide input to this proposal. The Guild would be willing to meet with the Department and the TGA to discuss these issues further.

Should you require any further information, please contact me or [REDACTED]

Yours sincerely

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