Pharmaceutical Society of Australia

6 May 2014

Ms Lisa Studdert
Head Market Authorisation Group
Therapeutic Goods Administration
[redacted]

Ms Julianne Quaine
First Assistant Secretary
Office of Health Protection
Department of Health
[redacted]

Dear Ms Studdert and Ms Quaine,

The Pharmaceutical Society of Australia (PSA) welcomes the opportunity to comment on the proposal to allow the registration and sale of invitro diagnostic devices (IVDs) for self-testing (home testing) for the presence of human immunodeficiency virus (HIV) in Australia.

PSA is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are over 28,000 registered pharmacists[i], of which approximately 80 per cent work in the community sector.

PSA supports the proposal to allow registration and sale of these devices with the aim of increasing detection of HIV in the community by enabling greater community access to tests that have been assessed for quality, safety and performance by the Therapeutic Goods Administration (TGA).

In recent years, community pharmacies have facilitated the distribution of screening kits and support services for conditions such as bowel cancer and chlamydia, as well as needle and syringe service. Studies in the ACT, Queensland and WA found that community pharmacies are effective in offering screening for chlamydia, particularly in areas where access to other health professionals, such as a GP or sexual health clinic, is limited. The studies also indicated that consumers valued the anonymity that can be offered by screening through a community pharmacy setting. In the Queensland trial, Emmerton et al found that the involvement of pharmacies in offering non-invasive sexually transmissible infection (STI) testing is considered important given their presence in the community, long opening hours, and trust and credibility as health-care providers and promoters[ii].

PSA believes that community pharmacies are therefore well placed to provide access to HIV self-testing devices under the guidance of a qualified and trusted health professional. However, we believe further consideration should be given to the issues outlined below before such a proposal is implemented.

- Identification of appropriate referral pathways to other health professionals (e.g. GP, family planning clinic, sexual health clinic) for consumers requiring additional information and/or timely support if a positive result is received;

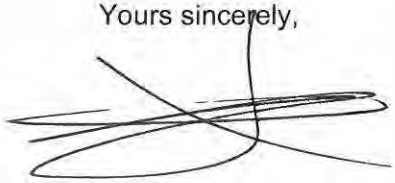
- Consumers and those approved to supply the kits would also need to be well-informed of the positive predictive values/false positive rate to assist them in understanding the

accuracy and sensitivity of the testing and how they can seek more information if they have questions or concerns;

- Comprehensive training and ongoing support for health professionals and support staff involved in the supply of the devices; and
- Guidelines and standards regarding appropriate counselling of consumers when purchasing the self-testing device.

Thank you for the opportunity to comment on this proposal. If you require any further information, or would like to discuss this submission in more detail please contact [redacted]

Yours sincerely,



Jan Ridd
Chief Executive Officer (Acting)

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[i] Based on data published by The Pharmacy Board of Australia in April 2014.

[ii] Emmerton L, Skinner M, Gardiner E, Nissen L and Debattista J. A trial of the distribution of chlamydia self-collection postal specimen kits from Australian community pharmacies. Sexual Health 2011; 8: 130-132.