



The Royal Australasian
College of Physicians

From the President

11 June 2014

Dr Tony Hobbs
Principal Medical Adviser
Australian Government - Department of Health
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Via Email: [REDACTED]

Dear Dr Hobbs

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[REDACTED]

- The RACP supports the proposal to allow the registration and sale of IVDs for HIV self-testing believing this has the potential to increase testing rates among populations that may not otherwise get tested. In addition, since IVDs not currently registered with the Therapeutic Goods Administration (TGA) are already being used, allowing the registration and sale of these devices via the TGA would improve the quality control of these devices.
- Whilst we recognise IVDs' inferior sensitivity and specificity, potentially rendering higher false non-reactive and reactive results compared to conventional serological testing at this time, the RACP believes the benefits of this proposal outweigh these potential issues. In addition, these risks can be mitigated with appropriate instructions for use, interpretation of results and follow up.
- We would also like to highlight that education efforts need to take into account the fact that some of those likely to access home testing may not identify with particular community groups where these efforts have typically been concentrated. Therefore, appropriate information and education resources need to be developed that will be acceptable to such 'hard to reach' populations.

- From a public health perspective, there is a need to consider how the registration and sale of IVDs for HIV self-testing might impact on national and state surveillance/monitoring of HIV testing and positivity rates. This is particularly important given the KPIs evaluating the national and state HIV Strategies' current emphasis on increasing HIV testing rates. We would encourage the Department of Health and the TGA to explore options for registering sales levels of these devices including location of sale where possible.

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