National
PATHOLOGY
ACCREDITATION
Advisory Council

MDP 951
GPO Box 9848
CANBERRA ACT 2601
http://www.health.gov.au/npaac

Telephone 02 6289 4017
Facsimile 02 6289 4028
E-mail: npaac@health.gov.au

Professor Chris Baggoley
Chief Medical Officer
Department of Health
GPO Box 9848 (MDP 84)
CANBERRA ACT 2601

Dear Professor Baggoley

Further to your correspondence dated 17 April 2014 seeking comments on the proposal to allow the registration and sale of in vitro diagnostic devices for self-testing for HIV, on behalf of the National Pathology Accreditation Advisory Council (NPAAC), I would like to provide the following comments for your consideration.

In response to the Phillips Fox report on Risks Associated with Non-Medicare Funded Pathology Testing, NPAAC identified Point-of-Care Testing (PoCT) to the Australian Health Minister's Advisory Council as an area of potential risk to patient safety and recommended consideration of a quality assurance framework for the performance of pathology tests that may be performed outside of a traditional pathology laboratory.

There are potential advantages to the use of PoCT devices, and in terms of HIV PoCT self-testing, there may the potential of reaching individuals who have not engaged with the health system to date. However, there are a number of potential risks to patient safety and the quality of test results that should be given further consideration–

- poor performance of self-administered tests, which may provide incorrect test results
- the testing would be performed by individuals that have no training, competency to perform the test or understanding of the implications of the test results
- no access to pre-test or post-test counselling
- with access to self-test kits, individuals may bypass confirmatory testing by an accredited pathology laboratory

In addition, there are currently discussions between relevant stakeholders, including TGA and NPAAC, on the development of a quality framework for the safe performance of HIV PoCT and quality test results for HIV PoCT for use by high risk

population groups to increase testing rates. There would potentially be disparity between the registration conditions of the current HIV PoCT test for target populations and the proposal for home testing by individuals. Accordingly, it would be recommended that some conditions are placed on the supply of HIV self-testing devices, noting the recent discussions on proposed amendments to the TGA conditions for the Alere HIV PoCT device. Any conditions should be considered in consultation with relevant expert groups, including pathology experts.

NPAAC would welcome the opportunity to provide any further advice on any safety and quality issues related to the proposed changes to allow registration of HIV PoCT devices for self-testing. I can be contacted through [redacted] Pathology Quality Section of the Medical Benefits Division on [redacted]

Yours sincerely

[redacted]

Associate Professor Paul McKenzie
Chair, NPAAC

6 May 2014

cc. Dr Tony Hobbs, Principal Medical Advisor, TGA
Dr Lisa Studdert, Head Market Authorisation Group, TGA
Ms Fifine Cahill, Primary Care, Diagnostics & Radiation Oncology Branch, MBD