



QPP

Queensland Positive People Inc

21 Manilla Street

EAST BRISBANE QLD 4169

PO Box 7403

EAST BRISBANE QLD 4169

AUSTRALIA

Friday, 2 May 2014

phone **07 3013 5555**

fax **07 3891 1830**

1800 636 241 (within QLD)

ABN 89 010 040 914

www.qpp.net.au

Lisa Studdert
Head Market Authorisation Group
Therapeutic Goods Administration

Dear Lisa

Thank you for the opportunity to respond to the proposal to allow the regulation and sale of intro diagnostic devices for self-testing for the presence of HIV. While I support this proposal to increase the detection of HIV in the community, much more must be done to eradicate HIV related stigma. The roadblocks that hold back the eradication of HIV stigma in the community will impact on all models for HIV testing, including the uptake of home-based testing for HIV.

An important benefit of home-testing is that it gives people another option for HIV testing and detecting HIV rates in Australia. An option that suits particular circumstances, especially with hard-to-reach population groups. The availability of home-testing could also encourage and allow people to test in the privacy of their own homes, potentially without concerns about their confidentiality. Self empowerment will hopefully be fostered giving individuals responsibility for their own healthcare. It must be noted that hard-to-reach population groups and individuals in isolated communities are affected more with the impact of HIV related stigma. Individuals will have ease of access, test as frequently as required, out of normal hours, and with a softening of the impact of HIV related stigma.

However there are several risks to home-based testing. Self harm or possibly suicide may occur because of inaccurate knowledge and information about HIV, together with the impact of HIV-related stigma in some situations. This is a real possibility when due process is not fully implemented. A major factor would be not having pretesting counselling. As mentioned before, hard to reach population groups often have a greater impact of HIV-related stigma and therefore will need additional support.

Allowing the TGA to approve such devices for HIV self-testing will be another option for the Department of Health to increase HIV detection rates in Australia. If a person discovers that they are HIV positive, all stakeholders, including HIV positive organisations, the federal government and the TGA clearly have a responsibility to empower individuals to seek treatment, ensuring that they keep themselves healthy, and keep others free of HIV. New partnerships must be established, especially with the National Association of People Living With HIV, Australia (NAPWHA) and its member state and territory organisations. The HIV positive organisations can successfully encourage people to follow up with treatment and counselling. Simple and clear non-medical information should form part of the home-testing process, and be written by people in the sector. The information could include contact details such as 13HEALTH, a website specifically dedicated to HIV home testing information and how to contact HIV-positive organisations. This information must be consistent in each jurisdiction.

Approval of HIV home-based testing, together with equitable access and consistency will help to ensure that only TGA endorsed suppliers of HIV home-based kits are accessed for the highest reliability.

Legislation will need to be changed to allow self-testing to occur. However legislation must also change concerning the criminalisation of HIV, if the uptake of self testing is to be successful. The criminalisation of HIV is one of the major roadblocks to eradicate HIV-related stigma. If you know you are HIV-positive you automatically put yourself into a position of possible liability and criminal charges. As you would appreciate, HIV is a health issue and must not be classified as a criminal issue. Furthermore the legislation should stipulate that plain packaging be used if the test kits are posted to people. The cost of home testing should also be equitable and accessible by being available to everyone's financial and geographical position.

The limitations and conditions must be seriously considered regarding various models and processes that may be approved. Consideration must be given to how the test kits will be acquired and how confidentiality will be maintained in that process. Another road block in eradicating HIV-related stigma is a fear of confidentiality being breached. [REDACTED]

[REDACTED]

It is very important to consider who will bear the cost. There is a high possibility that the lower the cost, the greater the uptake of home-based testing. Furthermore pre-test counselling must be mandatory and post-test counselling must be mandatory if the individual is diagnosed as HIV positive, to ensure that they keep themselves healthy.

Yours sincerely



Dr Peter Fenoglio
President
Queensland Positive People