MINISTRY OF HEALTH
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Lisa Studdert
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[redacted]

Dear Ms Studdert

Thank you for the opportunity to comment on a proposal being considered by the Therapeutic Goods Administration to allow the registration and sale of in-vitro diagnostic devices (IVDs) for self-testing (home testing) for the presence of human immunodeficiency virus (HIV) in Australia. The proposal is intended to increase detection of HIV in the community by enabling greater community access to tests.

The New Zealand Ministry of Health (the Ministry) agrees that early HIV diagnosis is better for the individual and for control of HIV in the community. It means that the most effective treatment can be offered, and that infected people can be advised to behave in safe ways.

HIV rapid test IVDs are being used in New Zealand. However, IVDs, including HIV rapid test kits, are currently excluded from mandatory notification to the Web Assisted Notification of Devices (WAND) database [1]. It is not known how many IVDs of this type are currently being supplied in New Zealand.

In 2012, the Ministry commissioned a national HIV conversation regarding HIV testing and pre-test discussion and post-test counselling. This process was well received by those working in the HIV sector and had a high level of engagement from the majority of key stakeholders in the HIV sector in New Zealand. It included involvement from infectious diseases clinicians, medical laboratory scientists, epidemiologists, experienced HIV rapid tests providers, sexual health clinicians and nurses, Family Planning clinicians, non-governmental organisations (including representatives of people who inject drugs, sex workers and the gay community), HIV service providers and support organisations for people living with HIV.

[1] The WAND database was established by the Medicines (Database of Medical Devices) Regulations 2003 to collect information about medical devices supplied in New Zealand. It is a mandatory requirement for importers, exporters and local manufacturers to notify their medical devices to the database.

The HIV sector strongly supported HIV rapid testing IVDs as an effective strategic approach for increasing testing rates and reaching those key affected populations, particularly the groups who are 'late presenters' for an HIV diagnosis. However, support was limited to the use of IVDs made available in a variety of accessible settings (for example, community organisations, general practitioners, sexual health services, etc) and administered by trained staff (who do not need to be doctors or nurses). This approach enables testing to be linked to the immediate offer of counselling for those who test either positive or negative (the former for emotional and practical support as well as safe sex advice, the latter to address risk taking behaviour). Training in the provision of HIV rapid testing was identified as a key priority in order to ensure that rapid testing service providers have a commitment to providing a quality, client focussed, and safe service.

Self-testing (home testing) for HIV was not supported by the HIV sector.

Specific comments in relation to some potential risks and concerns surrounding the use of IVDs for self-testing (home testing) for HIV are outlined below.

- Home testing creates a paradigm in which testing is isolated as an activity when in fact testing is part of an overall response to the HIV epidemic. Such isolation may have negative unintended consequences for HIV prevention in that people may reduce condom use, and as a consequence, the risk of HIV transmission may increase. The New Zealand AIDS Foundation (NZAF) has experienced clients who have used home testing as a 'warrant of fitness' for unprotected sex, weakening the culture of condom use within the men who have sex with men (MSM) community and risk increasing rates of infection. The concern is that this style of testing may encourage the prevention thinking that 'all you need to do is know your HIV status and then sero sort for sex'. This in turn would undermine the condom culture that has been built over many years and which has provided a most effective prevention strategy for MSM in both New Zealand and Australia.

- Home testing has issues associated with the care of people who test positive. A positive test can be a highly emotional and traumatic event and the person who has tested positive needs to be offered immediate support by way of counselling and advice. The NZAF reports that it has supported clients who have used IVDs and have been highly traumatised by a positive result and delayed support because the test occurred at home.

- The effectiveness of home tests is questionable because of the user error that can occur. The NZAF has experienced cases where clients have used home tests, then engaged in unprotected sex as a result, and then have been traumatised after relooking at the tests which by this time showed false positive results. This incident occurred due to misunderstanding about how to use the test.

- Linked to the comment above, the concept of home testing highlights the need for adequate instructions and understanding on IVD use and result interpretation, and for provision of information about organisations that can offer assistance and support for users of HIV home tests. Testing too soon in the infection cycle may

give a false negative result, and a false negative or positive result may result in potentially damaging behaviour on the part of the person tested.

- Increased use of IVDs for HIV testing may impact current HIV surveillance systems and thought would need to be given to ensuring information from IVD testing is contributed to the national surveillance programme.

Finally, in New Zealand every effort continues to be made to reinforce the 'condom message' amongst those at risk and encourage HIV testing to achieve early diagnosis, in order to get the benefits of treatment and care. However, in relation to HIV rapid testing IVDs, the Ministry favours access to this technology through rapid testing service providers who have a commitment to providing a quality, client focussed, and safe service.

Yours sincerely

Dr Don Mackie
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