

11 December 2014

DS20-14-0

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Dear Dr Hobbs

Thank you for the opportunity to comment on the consultation paper that outlines proposed performance expectations and risk mitigation strategies for tests used to detect HIV, particularly HIV point-of-care tests and HIV self-tests. The aim is to improve overall access to testing while still maintaining a high level of public health and safety.

The New Zealand Ministry of Health (the Ministry), as part of considering the consultation paper, sought external clinical advice from some members of the New Zealand Microbiology Network who have HIV testing expertise.

In terms of the performance expectations, the setting in which the test is used may affect the thresholds for performance expectations, as well as the sensitivity and specificity of the test. The Proposed Performance Requirements document does consider setting and the user as factors. The Ministry considers the proposed sensitivity and specificity thresholds to be reasonable.

Invited comments on the particular three sections are set out below.

1. *Performance requirements: whether or not you support the proposed requirements. If you do not support the proposed requirements you may make suggestions for alternative requirements that are acceptable to you and supporting reasons.*

Comment: The Ministry fully supports the proposed requirements.

2. *Risk mitigation strategies: an assessment of the suitability and likely effectiveness of the proposed risk mitigation strategies to be employed by manufacturers to allow a risk/benefit assessment of the device. If you do not support the proposed*

risk mitigations strategies you may make suggestions for amendments to the proposed risk mitigation strategies or suggestions of additional risk mitigation measures.

Comment: The Ministry supports the proposed risk mitigation strategies. However, possible problems are perceived with the expectation that manufacturers and / or sponsors provide the Therapeutic Goods Administration with data around false negative or false positive results on HIV self-tests. The Ministry is unsure of the logistics that would ensure this is even possible.

3. *Conditions of approval: whether or not you support the proposed conditions of approval. If you do not support the proposed conditions you may make suggestions for alternative conditions that could be considered.*

Comment: The Ministry fully supports the proposed conditions of approval.

Overall, the Ministry considers that the document is very good and covers all relevant issues of concern.

Yours sincerely



Dr Don Mackie
Chief Medical Officer
Clinical Leadership, Protection and Regulation