Email record of verbal conversation between Dr Lisa Studdert (Therapeutic Goods Administration) and Professor John E.J. Rasko, AO.

Dear John,
Thank you for your call last week and offer to discuss the proposal to review policy and regulatory provisions for access to HIV home self-tests in Australia.

As per your offer, I am providing this email with a brief account of our conversation for you to confirm or modify.

You asked if the proposal was for policy/regulatory amendments specific to HIV home self-tests and I confirmed that yes, at this stage, that is all that was in scope.

You noted that there was some precedence such as with home-tests for pregnancy and that to some extent, some of the issues, risks and sensitivities were similar. However, it is also must be recognised that there is still a lot of stigma around HIV and you saw this everyday in the way test results are delivered to you as a medical practitioner who has ordered a test - still in paper, within a sealed envelope - noting this was the only test result still delivered this way.

You went on to note that in your view, this development was probably inevitable and it was a matter of timing and, importantly, the safeguards and standards adopted in conjunction with it. There should be some consideration of the potential for the test to be used surreptitiously, without the consent of the person being test (particularly in relation to a saliva test, should it become available), but in our conversation we noted that this could/should be addressed through some advice within the test packaging/information about the legality of such an action and thus, risks associated.

You also noted that information provided with the test and/or on an associated website would need to provide advice to the user on follow-up actions e.g. a hotline to call, website to refer to, to contact a medical professional, and, some information about ongoing safe-sex practices.

Finally, you noted that there had to be great care taken with the implementation of the policy, that it was recognised one-size-fits-all testing was not appropriate, blood tests by accredited providers remain the gold-standard and that the acceptable cut-offs for sensitivity and specificity needed to be considered.

I trust this is an accurate account of your comments but please feel free to amend/add/delete accordingly.

Thank you again John for your input on this consultation - it is much appreciated.
Kind regards,
Lisa

Lisa Studdert, PhD
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TGA Executive