

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2015 - 16, 10 February 2016

Ref No: SQ16-00012

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Pre Exposure Prophylaxis (PrEP)

Type of Question: Hansard Page 115, 10 February 2016

Senator: Simms, Robert

Question:

Are you aware of any PrEP trials scheduled for South Australia? Is there any work being done in the state of South Australia in that regard or with provision of rapid testing?

Answer:

The Therapeutic Goods Administration (TGA) has not received a notification under the Clinical Trial Notification (CTN) Scheme for any current Pre Exposure Prophylaxis trial which has clinical trial sites situated in South Australia and has been advised by the South Australian Chief Health Officer that there are no trials currently being undertaken in that state. The TGA has not received any advance notice (and would be unlikely to receive advance notice) of a planned trial.

Three HIV rapid tests for use at the point of care have been included in the Australian Register of Therapeutic Goods (ARTG) and can be legally supplied in Australia. These tests are for use under the supervision of a health care professional and are not approved for self-testing:

- Uni-Gold HIV point of care test (PoCT);
- Determine HIV PoCT; and
- OraQuick ADVANCE HIV PoCT.

HIV self-tests can now be included in the ARTG and legally supplied in Australia, subject to satisfying the applicable regulatory requirements. As yet no applications have been received for marketing approval for supply of an HIV self-test in Australia.