Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2015 - 2016, 10 February 2016

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

Topic: PrEP

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Senator: Simms, Robert

Question:

Senator SIMMS: Just while we are on the matter of PrEP, you might be aware that, in November of last year, the Senate passed a motion calling on the government to look at regulatory barriers for access to PrEP and rapid HIV tests and home self-tests. I am interested to know from the TGA, Professor Skerritt, about what investigations are happening in terms of availability of PrEP, but I am also keen to hear from the minister about what action the federal government has taken since the passage of the motion in the Senate last year.
Senator Nash: I am not aware. I will have to take that on notice for you. But I am very happy to do that for the minister. I will pass to the professor.
Senator SIMMS: Thank you. I appreciate that.

Answer:

PrEP

TRUVADA was approved in Australia for the treatment of HIV in adults over the age of 18 on 22 September 2005. Truvada is currently PBS listed for the treatment of HIV. The company chose not to provide the PrEP application at the same time in Australia as the application for use of the drug in treatment post infection. That was a commercial decision on their part.

However, to extend the use of a medicine already registered in Australia, it is necessary for the sponsor of the product to submit an application to the Therapeutic Goods Administration (TGA) with safety and efficacy data supporting the use of the additional indications. This is a commercial decision for the sponsor of the product, Gilead Sciences Pty Ltd.

The TGA is currently evaluating a submission made by the Australian sponsor, Gilead Sciences Pty Ltd to extend the currently approved indications to treat pre-exposure prophylaxis of HIV. This application is due to be discussed as an item by the Advisory Committee for Prescription Medicines (ACPM) at the April meeting. A decision in relation to this submission is due May to June 2016. Should approval be granted, registration and marketing of the newly approved indications will occur shortly after.

The Pharmaceutical Benefits Advisory Committee (PBAC) did not receive an application for consideration of PrEP at its March 2016 meeting. The next PBAC meeting will be held in July 2016. The PBAC meeting agenda is made public on the Pharmaceutical Benefits Scheme website around 10 weeks before each meeting.

HIV Self-Tests

HIV self-tests can now be included in the Australian Register of Therapeutic Goods and legally supplied in Australia, subject to satisfying the applicable regulatory requirements. We have not received any applications for marketing approval for supply of an HIV self-test in Australia.

We have approved three HIV point of care tests (PoCTs) for use under the supervision of a health care professional; these are not self-tests. The Uni-Gold and Determine HIV PoCTs are approved for use with fingerprick blood specimens while the OraQuick ADVANCE HIV PoCT can be used with fingerprick blood or oral fluid. The availability of point of care testing plays an important role in increasing access to testing for high risk groups.

In November 2014, we consulted stakeholders to assist in the development of a pre-market assessment model so that there is a clear understanding of the TGA's performance expectations for all forms of HIV tests, particularly HIV PoCTs and HIV self-tests.

Stakeholders were also invited to comment on appropriate risk mitigation strategies for HIV PoCTs and HIV self-tests to ensure that efficacy is maximised in these settings.

In March 2015, we published the guideline document 'Clinical performance requirements and risk mitigation strategies for HIV tests'. The document will assist industry to submit applications for marketing approval.