Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2015 - 2016, 10 February 2016

Ref No: SQ16-000083

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

Topic: Therapeutic Goods Administration

Type of Question: Written Question on Notice

Senator: Gallagher, Katy

Question:

a) There is an application now before the TGA and the Pharmaceutical Benefits Advisory Committee for an alternative use, to prevent transmission in HIV negative people – also called PrEP. Can you update the committee where that process is up to?
b) There are a number of demonstration trials underway – in Queensland, NSW and Victoria. I understand that the evidence about PrEP has been fairly conclusively demonstrated in international studies. What are the Australian trials investigating?
c) Are the Australian trials feeding into the TGA and PBAC process?
d) Will the extension and expansion of the existing trials in any way delay the TGA and PBAC consideration?

Answer:

a) The Therapeutic Goods Administration (TGA) does not provide public comment on the status of applications, or whether applications have been received due to confidentiality requirements restricting the release of information, this is a matter for the individual sponsor to provide. The Pharmaceutical Benefits Advisory Committee (PBAC) has not received an application for consideration 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.

b) Information available from the Australian and New Zealand Clinical Trials Registry (ANZCTR) on the Queensland and NSW trials is:

- The Queensland trial is examining the results of the Pre-exposure prophylaxis (PrEP) clinical trials in the "real world" setting to show that PrEP is a feasible, safe and effective method for reducing the risk of HIV acquisition in the Queensland community. The QPrEP demonstration project will address this need.

- The New South Wales trial (the PRELUDE study) will analyse the feasibility of PrEP delivery, adherence to the study medication, safety and tolerability, the effects of PrEP use on behavior, and statistical analyses of the risk of HIV seroconversion

The latest Victorian study announced on 30 January 2016 is Pre-exposure Prophylaxis Expanded (PrEPX) which is a new study sponsored by the Victorian Government, Alfred Health and the Victorian AIDS Council. It is being designed to examine the impact of expanding the use of PrEP on the rates of new HIV infections in Victoria. The PrEPX study aims to offer PrEP to up to 2,600 people at high risk of HIV infection. The study will need to be approved by relevant bodies and it is anticipated that it will start enrolment in mid-2016. PrEPX will enrol people whose sexual or injecting drug use activities mean that they have a high chance of acquiring HIV infection.

c) Sponsors can use a range of data as part of an information dossier they submit to the TGA for registration. Where a clinical trial is completed, or information from it can be used at the time of submission, this can include data from clinical trials. This is also the case for submissions for PBAC consideration.

d) The demonstration trials underway in Australia will not impact the TGA registration process. Assessment of any submission will be based on information supplied to or considered by the TGA (or the PBAC) at the time of a submission.