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Supporting the HIV, Viral Hepatitis and Sexual Health Workforce

PBAC announce deferment on HIV Prevention Drug

Media Release

19 August 2016

The [Pharmaceutical Benefits Advisory Committee \(PBAC\)](#), the key committee of experts which advises announced that it has deferred the application from Gilead Sciences and Mylan Australia to have their products approved for HIV Pre Exposure Prophylaxis (PrEP). PrEP takes the form of a daily tablet containing tenofovir and emtricitabine and, when used daily reduces the risk of HIV transmission by up to 99%.

Background

The application for a listing of **Gilead Sciences' Truvada®** was first rejected in August 2016 by the PBAC who indicated concerns with unacceptable and uncertain cost-effectiveness based on the target populations and the price proposed in the 2016 submission. Truvada® was determined safe and effective by the **Therapeutic Drugs Administration (TGA)** – the Australian Department of Health regulatory body of therapeutic goods – in May 2016.

In December 2016, **Mylan** and **Lupin** had their generic versions of co-formulated tenofovir and emtricitabine registered for use as PrEP by the TGA. PrEP has been available to individuals in Australia for several years via PrEP demonstration trials in several Australian States and Territories and via personal importation of generic PrEP. The PBAC has not rejected the applications, but has deferred its decision as it seeks further information on the number of people likely to use PrEP and conducts price negotiations. PBAC has accepted that PrEP is effective in preventing HIV transmission.

In their notes to Mylan, the PBAC reiterated that it was seeking the cost-effectiveness analyses noted above. Of note, PBAC did not state that Mylan's asking price for PrEP had an influence on Mylan's cost-effectiveness analysis.

The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) – the peak body representing the clinical HIV workforce – believes that there is an urgent continuing priority to make PrEP available across all jurisdictions in Australia until HIV PrEP becomes listed on the PBS for HIV prevention. We confirm a commitment to work collaboratively to advocate for prompt and equitable access to HIV PrEP which continues to bring benefit to individuals and to the Australian population.

“ASHM will continue its commitment to advocate for affordable access to HIV PrEP with the ultimate outcome of a PBS listing – allowing people-at-risk of HIV to no longer pay high, unsubsidised prices, nor have to import low-cost generic drugs from overseas using the TGA's Personal Importation Scheme,” said ASHM President, Professor Mark Boyd.

General practitioners, sexual health physicians, hospital specialists and nurses have already played a major role in providing PrEP to those in need through the current PrEP access studies across Australian States and Territories.

“What a PBS listing would mean for clinics like mine – which is part of [EPIC-NSW](#) (*Expanded PrEP Implementation in Communities in NSW*) – a PrEP access study that targets high-risk populations, is that we, as medical providers, could continue to offer this safe and effective prevention measure to our patients,” said ASHM President-Elect, Dr Mark Bloch, who practices at one of the study's access points, Holdsworth House Medical Practice, Sydney.



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“We know PrEP works through evidence of such trials,” Dr Bloch continues. “[EPIC-NSW](#) has been making a real impact as per the data published in the first quarter of 2017 which indicates that NSW new HIV diagnoses are down 30% in high-risk MSM (men who have sex with men) populations and this second quarter data is expected to show even further improvement.”

“ASHM now aims to encourage ongoing collaboration and PBAC re-submission by proposing a round table with PBAC and all stakeholders – to explore the remaining issues,” said ASHM CEO, A/Prof Levina Crooks. “We now aim to re-activate a PrEP Working Group to decide on the best approach to get this approval finally over the line and will work with all key stakeholders and across Australia to achieve this.”

“People must understand that the PBAC application deferment is **not an indication that PrEP is not safe or that PrEP is not effective**. PrEP is the most efficacious prevention strategy that is available preventing a person from acquiring HIV”.

“PBAC’s decision announced today to defer a recommendation on subsidising PrEP products from Gilead Sciences and Mylan is a minor setback,” said A/Prof Edwina Wright, leader of the [PrEP X Demonstration Project](#) in Victoria.

“Australia is leading the world with PrEP in terms of its roll out of PrEP, its community attitudes towards and knowledge of PrEP and in the strength of the relationships between government, community, activists, peak organisations, clinicians, scientists and researchers around PrEP,” A/Prof Wright continues.

“What Australia has done is remarkable. We have over 12,000 people currently on PrEP which is almost **one third** of the estimated number of people in Australia who are eligible for PrEP.”

When used daily, PrEP reduces HIV transmission by up to 99% and no other HIV prevention method offers this level of protection. ASHM need this prevention tool to be available to all Australians and only PBS listing will achieve this outcome. Until then we will continue to expand access to PrEP via PrEP trials and by supporting individuals who are importing PrEP.

[Access Link to Clinical Resources supporting the HIV workforce](#)

ASHM continues to support the workforce to ensure access to PrEP (either through trials or personal importation) and best practice in guidelines, training and resources:

- In July 2017, new **ASHM Australian HIV Pre-exposure Prophylaxis (PrEP) Clinical Guidelines** have been published in the **Journal of Virus Eradication** ([Journal of Virus Eradication 2017; 3: pp168–184](#)) for clinicians who will be initiating and monitoring people taking PrEP and are designed to reflect Australia’s epidemiology.
- All clinicians interested in accessing training on HIV PrEP can register to join ASHM’s Online Learning Module – ‘**PrEP in practice: Guidance for GPs**’ (Duration: 40 to 60 minutes) via the ASHM Learning Management System: <https://lms.ashm.org.au/enrol/index.php?id=69>
- Currently in development are new at-a-glance **HIV PrEP resources for clinicians and patients** soon to become available via <http://ashm.org.au/HIV/PrEP/>

[Further Information on PrEP trials and the Personal Importation Scheme](#)

ASHM are committed to informing people at risk of HIV on how they can access PrEP while the application process continues. Find links to further information:

Information about Personal Importation Scheme:



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<https://www.tga.gov.au/personal-importation-scheme>

Jurisdictional Information on how clinicians can support patients accessing PrEP can be found at http://www.health.wa.gov.au/circularsnew/circular.cfm?Circ_ID=13251

People at high risk of acquisition of HIV from Victoria can join the *PrEPX* Study:
<https://www.alfredhealth.org.au/research/research-areas/infectious-diseases-research/prepx-study>

People at high risk of acquisition of HIV from South Australia can join the *PrEPX* Study:
<https://www.alfredhealth.org.au/research/research-areas/infectious-diseases-research/prepx-south-australia>

People at high risk of acquisition of HIV from NSW and ACT can join the *EPIC* Study:
<http://endinghiv.org.au/nsw/stay-safe/prep/>

People at high risk of acquisition of HIV from Queensland can join *QPrEPd*:
<http://www.comeprepd.info/>

Contacts available for further comment:

Prof Edwina Wright (ASHM Clinical Advisor on PrEP)
Dr Mark Bloch (ASHM President-Elect)

0414 242 600 (VIC)
0423 290 428 (NSW)

About ASHM

Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) is a peak organisation of health professionals in Australia and New Zealand who work in HIV, viral hepatitis and sexually transmissible infections (STIs). ASHM draws on its experience and expertise to support the health workforce and to contribute to the sector, domestically and internationally.

www.ashm.org.au