



Creating A Competitive Pricing Environment To Enable Access To PrEP in Australia

Theme D Proffered Paper Session 4: Funding, Policy & Advocacy in the Contemporary Environment

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Subsidised and Universal Access to Healthcare in Australia: The System

- PBAC recommends medication for PBS listing in response to submissions from industry
- The recommendation is based on cost effectiveness of medication based on public health value
- The system is reactive: Government or a statutory body cannot approach industry to initiate an application for subsidisation of their product.

PrEP in Australia before 2016

- First Australian PrEP trial, VicPrEP in May 2014 followed by a slightly bigger trial, PrELUDE, in NSW in early 2015
- Community led organisations commenced community activities to raise awareness of PrEP
- In 2015, the NSW and Victorian health departments initiated larger trials
- Outside of Melbourne and Sydney information and drug access was scarce
- To maximise the potential of PrEP access had to be **rapid, scaled up** to population size and **targeted** to key populations.

PrEP IN 2016: rapid mobilisation in the east coast capitals, 1st attempt at PBS listing

- Supply through trials could not keep up with demand
- we needed PrEP access to be equitable, and integrated through the PBS
- In March 2016, Gilead Sciences' made a submission to the PBAC for PBS listing
- In May 2016 Truvada as PrEP was registered on the ARTG
- In July 2016, Gilead Sciences' submission was declined on the grounds of a lack of:
 - local evidence to support the efficacy and use of Truvada among gay and bisexual men
 - evidence around the safety of long-term dosing of Truvada.
- AFAO immediately responded to the outcome by working with:
 - research partners to commission modelling of the numbers of PrEP users in Australia
 - clinical partners to inform changes to PrEP clinical guidelines
 - industry to advocate for a fresh submission.

PrEP IN 2017

- Uncertainty around a fresh submission to the PBAC for PBS listing
- funding for some interim access trials was exhausted.
- In early 2017, there was no guarantee of ongoing access to PrEP, nationally – other than through personal importation or paying the prohibitive cost of the medication over the counter with a private script.
- Both options were unsustainable for the purposes of enabling **rapid, scaled up and targeted** access to PrEP.
- Australia desperately needed federally subsidised access to PrEP if we were to:
 - meet community demand; and
 - have any chance of virtually eliminating HIV transmission.

The Operating Environment

- Gilead Sciences' patent on Truvada as PrEP: expiry and the opportunity for industry competition
 - July 2017 Gilead Sciences' patent on Truvada expired
 - The expiration provided a window into a new operating environment: market competition
 - AFAO proactively encouraged generic manufacturers of Truvada to prepare submissions to the PBAC for PBS listing
- PrEP medication for the purposes of PBS listing
 - the concept of HIV PrEP was new, the drug formulation was not
- Industry: Truvada as PrEP, the PBAC and generic suppliers
 - Generic manufacturers are less familiar with the PBAC regulatory framework
 - AFAO worked with generic manufacturers to ensure they were fully informed about the research and the requirements of the regulatory system

At the level of government – complexity

- The Regulator, the PBAC, whose authority is to determine a cost-effective price
- The Department of Health, whose aim, in relation to HIV, is to implement public health initiatives to address HIV
- state and territory governments who were keen for the Commonwealth to assume responsibility for funding PrEP
- All three of these arms of government were operating within scope, but no single arm could actively pursue an industry application to the PBAC for PBS listing
- AFAO and NAPWHA actively worked with stakeholders to unlock the paralysis and progress the situation towards a PBS listing

The role of civil society organisations. Working for a public interest outcome

- AFAO and NAPWHA have a history of developing structured and informed strategies to improve health outcomes for our communities.
- both organisations played an intermediary role between industry and the various arms of government to broker a resolution
- Civil society organisations are uniquely placed to work with multiple and diverse stakeholders to broker outcomes that are in the public interest.