

Message to *PrEP in Europe Summit* participants – from AFAO & Australian PrEP advocates

Date: 09 February 2018

Dear Gus and PrEP in Europe,

Today the Australian Government agreed to include PrEP and its subsidisation listing through Australia's Pharmaceutical Benefits Scheme (PBS).

We think this was auspicious timing given the *PrEP in Europe Summit* also starts today.

The overall outline of the Government's decision is covered in AFAO's Media release (attached). We think the Government's decision includes everything that AFAO proposed to the Government – wide accessibility (through all general practitioners, sexual and other public health clinics and pharmacies; access for any Australians assessed as high *or medium* risk; and subsidization at standard cost for pharma scripts (currently A\$40; US\$30 per month).

However, what we thought may be more useful for your Summit was outlining some of the strategies and potential lessons for advocates in other countries achieving similar outcomes – particularly as advocates from across Europe will be all together today and tomorrow.

So what follows is a brief outline of the background of advocacy and negotiations in Australia – and then some strategies and lessons our advocates learned or devised in order to achieve a successful result.

Brief background on PrEP in Australia.

While there was considerable discussion and advocacy about PrEP through 2012 to 2016, neither the national nor the state governments considered it seriously given the price of Truvada.

However, during 2016 Gilead Australia decided – for unexplained reasons - not to renew its patent on Truvada beyond August 2017. (Note: we are very well aware this was *not* the case in all or most of Europe.)

AFAO led other community organisations and allies from research and clinical agencies (and assistance from some State government department personnel) in mounting the case for wide PrEP accessibility and its subsidization.

The Australian Government did not indicate any significant interest so the New South Wales Government decided to institute and fund its own PrEP access 'trial' – and rapidly enrolled thousands of gay men. Other states soon followed this

initiative. There are now currently more than 15,000 Australians on PrEP, chiefly gay men.

By mid-2017 the Australian Government realized its lack of leadership was becoming embarrassing and agreed to invite applications from pharmaceutical sponsor organisations for listing Truvada on the PBS List. Three pharma companies indicated initial interest: Gilead, and the generics companies Mylan and Lupin.

The PrEP applications and negotiation process:

Only Gilead and Mylan submitted applications on the price they sought for PrEP. Gilead proposed their full market price (which would be still in effect in Europe currently, as most countries the Truvada patents were extended) while Mylan – disappointingly – proposed a quite similar price.

In November 2017, the decision-making body – the Pharmaceutical Benefits Advisory Committee (PBAC) – rejected the two applications on the basis of lack of return on investment, quite properly.

But crucially, the PBAC did not abandon the applications process. Instead, they sought further negotiations with the potential suppliers and asked for revised applications.

The AFAO & Community Advocates Response:

The AFAO advocates re-engaged in negotiations with generic company Lupin and were successful in persuading it to submit a substantially lower price. [About A\$470 (US\$360) per year rather than A\$10,000 (\$8,000) per year.

The PBAC accordingly accepted the Lupin application today and the arrangements for listing and full accessibility will be in place within several months. (Meanwhile the state-based ‘trials’ will continue for the current 15,000+ participants.)

Some Lessons Learned in the Australia negotiations:

- Encouraging state, provincial or even municipal agencies to initiate PrEP Accessibility programs can put pressure on national governments to provide leadership – especially when credible Return-on-Investment analyses indicate substantial financial savings;

(Note: AFAO is strongly encouraging Quezon City (in Metro Manila, Philippines) in their well-developed plans to initiate its wide PrEP accessibility in their municipal territory (4-5 million) as soon as possible.

- The dramatic price reduction achieved for Truvada – from A\$10,000 (US\$8,000) per year to A\$470 (US\$360) can be used by all PrEP advocates as a maximum starting point – and argue downwards as more competition develops among the generic producers.
 - Quick background:
 - Somewhat surprisingly, the Australian National Pharmaceutical Benefits Scheme (PBS) is the world’s largest single purchaser of pharma drugs globally – so the pharma giants hate it as its volume requirements enable it to in effect set the floor price for each new drug because it routinely has the largest volume to negotiate for; global pharma companies ensure elsewhere that ijoph[‘they routinely negotiate directly with individual hospitals, clusters of hospitals or, rarely, state or provincial governments.
- Advocates in-country should develop relationships with in-country offices of Gilead **and** with branch offices of generic pharma companies, which are steadily increasing in number;
 - Note: ITPC may be able to assist with identifying where generic companies have offices in specific countries;
- Creating competition among the various generic potential providers can have very significant benefits in price reduction – perhaps even greater than in Australia, especially in Low Income countries;
- Gilead is not a global ‘concrete monolith’ - some staff in Gilead in-country offices can be more flexible and supportive than the head office staff;
- Identifying allies in the clinical, research and governmental sectors is critically important in fostering advocacy from different sectors;
- We also encourage the *PrEP in Europe Summit* to canvass ideas on helping establish a mechanism to pressure Gilead to cease extending Truvada patents in all countries; perhaps a ‘confrontation’ at the AIDS2018 Conference (in partnership with ITPC, MSMGF and other allies).

Best wishes
Don

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