

Senate Finance and Public Administration Committee

13 July 2011

Inquiry into the Government's Administration of the Pharmaceutical Benefits Scheme (PBS)

About Positive Life NSW

Positive Life NSW is a community-based non-government organisation funded by NSW Health. It has represented the interests of people with HIV in NSW since 1988. Positive Life NSW provides advocacy to government and non-government agencies on a range of HIV and related health and social issues. It also develops HIV prevention, education and support programs that focus on improving the health and wellbeing of people with HIV in NSW.

People with HIV in NSW

The total number of people diagnosed with HIV in Australia was estimated to be 20,956 in 2010. By 2020, the total number of people living with HIV in Australia is predicted to be 28,422. This does not account for the 10-20% of HIV infections that are thought to be undiagnosed¹. NSW is the state with the highest number of people living with HIV, with 9,924 people in 2010. This number is estimated to increase to 11,721 by 2020².

The deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee and the consequences for patients of such deferrals

HIV

The control of HIV is dependent on combination antiretroviral therapy. Antiretroviral therapy (ART) for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection has improved steadily since the advent of combination therapy in 1996. Research indicates that 80% of people with HIV are currently taking ARV therapy³. More

¹ Wilson D. (2010) *Mapping HIV outcomes: geographical and clinical forecasts of numbers of people living with HIV in Australia*. National centre in HIV Epidemiology and Clinical Research, National Association of People Living with HIV/AIDS, p 5

² Ibid, p5

³ Grierson J et al., (2009), *HIV Futures Six – Making positive lives count*, Australian Research Centre in Sex, Health and Society, La Trobe University, p14

recently, new drugs have been approved that offer new mechanisms of action, added potency, dosing convenience, and improved safety profiles. Popular drugs are being used less often as their drawbacks have become better understood and defined. Resistance Genotypic and Phenotypic assay tests are being used more commonly in clinical practice and interactions among antiretroviral agents and other drugs have become increasingly complex. These issues have reduced prescribing options in some patients.

The *'Guidelines for the use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents'* have been developed by Australian experts and reviewed by the Office of the AIDS Research Advisory Council (OARAC). Recommendations are based upon expert opinion and scientific evidence. To be successful, antiretroviral regimes need to contain at least two, but preferably three, active drugs from multiple drug classes. If suppression is lost due to viral mutation, changing to a new regime is clinically indicated⁴.

Many patients with HIV successfully maintain viral suppression on a stable combination of ART. Some patients however have difficulty maintaining viral suppression due to extensive previous exposure to multiple drug classes, or from interactions (side effects) associated with other prescribed medications. For these patients, access to new drugs that use different mechanisms to control HIV is essential in preventing mortality.

It should also be noted that the costs associated with primary and acute health care resulting from a delay in the approval and availability of new drugs to effectively control HIV, together with the loss of productivity due to morbidity, would significantly militate any cost saving measures in the PBS budget.

The Role of PBAC

The Pharmaceutical Benefits Advisory Committee makes recommendations to the Minister about which drugs and medical preparations should be made available for listing on the PBS. The Committee considers the effectiveness and cost of a proposed benefit compared to alternative available therapeutic drugs. When recommending listings, the Committee provides advice to the Pharmaceutical Benefits Pricing Authority (PBPA) regarding comparison with alternatives and their cost effectiveness.

Positive Life NSW believes that deferring approval for ARV medications that have been recommended for listing by the PBAC, will limit access to new drugs for people with HIV whose therapeutic options are either limited or have run out. Severe consequences for the health of these individuals may result.

⁴ Guidelines for the use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents, 2008, Office of AIDS Research Advisory Council (OARAC)

Other Health conditions

People with HIV also frequently manage a range of other co-morbid health conditions. Australian research has identified that nearly half of all people with HIV (46%) indicate that they have a major health condition other than HIV/AIDS⁵. The most common conditions are cardiovascular, diabetes, liver and kidney disease, cancers, neurocognitive impairments, depression and anxiety and bone disease. Treatment is frequently recommended for the control of these conditions. Potential interactions between ARV medications and the medications prescribed for other health conditions can become complex and further restrict prescribing options.

Consequences for the Pharmaceutical sector and impacts on the future availability of medicines in Australia

Research and development by the pharmaceutical industry and applications made for PBS listing of new and improved ARV drugs have been helped in Australia by a stable approvals regime. The effectiveness and cost of a proposed drug is considered in relation to alternative therapeutic agents by a panel of experts. Recommendations from PBAC and PBPA are provided to the Minister on the basis of merit.

Positive Life NSW believes that this system of approvals has served the Australian Health System well. The PBAC recommendation and approvals process is envied in many developed countries throughout the world as an efficient and cost effective mechanism to maintain a balance between the health needs of Australians and costs to taxpayers.

We also believe that changes to the mechanism for approvals could potentially undermine the confidence of pharmaceutical companies to develop new and improved drugs. Additionally we are concerned that these changes may discourage pharmaceutical companies from making applications for the listing of new drugs in Australia.

Recommendations:

We believe that the Minister for Health should grant approval for drugs (in a timely manner) that have been independently assessed and recommended by the Pharmaceutical Benefits Advisory Committee for listing by the PBS.

Positive Life NSW supports a reversal to the prior approvals process for the following reasons:

⁵ Grierson, J et al., (2009) *HIV Futures Six – making positive lives count*, Australian Research Centre in Sex, Health and Society, La Trobe University, p6

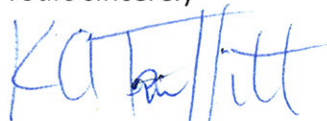
- Timely access to new ARV medications is essential for people who have run out of, or have limited prescribing options to control viremia, morbidity, mortality and the transmission of HIV.
- Interactions between ARV medications and medications used for the treatment of other health conditions (e.g. cancer, cardiovascular disease) reduce treatment options when PBS listings of new and innovative medicines have been held up.
- Expedient access to effective drugs prevents illness progression and reduces primary and acute health care costs.
- Research and development of new drugs and applications for PBS listing by pharmaceutical companies may be negatively impacted as a result of deferrals and lack of confidence in the approvals process.

Conclusion

Positive Life NSW would like to thank the Senate Finance and Public Administration Committee for the opportunity to provide comment to the Inquiry on the Government's Administration of the Pharmaceutical Benefits Scheme (PBS). We would be happy to provide further information in relation to this submission if this is required. Please contact Lance Feeney – Systemic Advocacy and Policy on (02) 9361 6011 or email lancef@positivelife.org.au

We also would like to refer the committee to the submissions made by NAPWA, AFAO and ACON.

Yours sincerely



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