

Senate Finance and Public Administration Committees

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

The National Association of People Living with HIV/AIDS (NAPWA) is grateful for the opportunity to provide these comments to the Finance and Public Administration References Committee. These matters are critical for the Australian population, as every Australian is a health consumer and many Australians at some point in their life require the access to health care and medicines which the Pharmaceutical Benefits Scheme provides. The system supporting this scheme has been acknowledged in Australia and internationally as one which has robust cost controls while sustaining prescription medicine supply to patients. The consequences for patients of the current drug deferral actions is immediate and shocking for those directly impacted, and awaiting access to these medicines. The consequences for patients ongoing, and for those in the future is devastating on many levels. Australia can afford a fair and reasonable process for ensuring best possible health outcomes can be delivered to the populations of need. Australia cannot afford to see medicines beyond the reach of many sick and vulnerable patients.

NAPWA believes that the deferral of listing for drugs recommended for the PBS is shortsighted, and disturbing as an ongoing precedent and interference in the regulatory approval arrangements. We strongly support a reversal of these decisions, and a strengthening of commitment to the PBS listing process that maintains the integrity of that process.

People living with HIV are dependent on a suite of highly potent and specific medications known as HIV antiretrovirals. These drugs are prescribed by restricted authority under S100 prescribing arrangements, and the drugs chosen for each person are selected in accordance with a range of specific patient needs and drug sequencing guidelines. HIV antiretrovirals are prescribed under a clinical management paradigm known as "combination therapy", and this therapy has advanced in recent years to now deliver significant life extension to the treating population, with improvement in clinical outcomes for those who are able to suppress viral progression and better protect their immune system.

Effective treatment of HIV has also been shown to have secondary, public health benefit. As the health of a person with HIV is improved the amount of virus they carry is reduced to very low levels, thus making onward transmission of the virus very difficult.

The ongoing improvements in drug targeting, and better efficacy of HIV treatments is a critical factor in these results for patients. It should be noted that a drug pipeline offering improvements in outcome and life enabling responses for any patient group is only as good as the system ensuring these drugs becoming available to the patients concerned. In Australia the PBS processes have been the enabling architecture for these advances to reach the population, across all disease areas.

NAPWA is committed to the Australian Pharmaceutical Benefits system as a system which has been strengthened and improved over the years to be highly effective in controlling costs, while also ensuring that the most appropriate and efficacious medicines are made available to Australians in a timely manner. In Australia, every HIV drug, and many other medications for the clinical management of HIV associated conditions, are listed under the arrangements of the Pharmaceutical Benefits Schedule. People living with HIV are literally life dependent on the provision of drugs under this scheme, now and into the long-term future.

This year has seen a disturbing interference in the formal and understood PBS listing processes. The Australian Government announced a decision on the 25th February 2011¹ to defer the listing of a number of these new medications, and also stated that it would now be requiring all new PBS listings with a net cost to Government to be approved by Cabinet.

This announcement was made unexpectedly and critical changes were implemented without consultation to the collaborative partnership of health consumer groups, including the body of the Consumers Health Forum, and with specific patient groups such as NAPWA. These groups have worked solidly in partnership with Government to show strong support for PBS reform procedures in particular over recent years. The decision came at a time when there was wide speculation as to the whether the driver of this was linked to budgetary factors associated with preparation for the May 2011 budget release, or whether there were more changes being planned across the PBS structure itself.

In short, this led to wide concern and anger across the patient community, and was insensitive to the general concerns of the population as it deals with rising costs of health care, barriers to effective access to treatments and care, and contested health debates about health spending priorities².

Deferral of listings of approved drugs on the Pharmaceutical Benefits Scheme is of concern because of a number of issues, but it is also important to state that the process of deciding to defer listings, the lack of transparency related to the Government's decision, and the timing of the announcement of this decision, was damaging to a notion of partnership and trust between Government and affected stakeholders. The decision is also confusing in terms of the rationale and placement of these changes prior to delivery of a formal Commonwealth Budget, and outside of the scope and processes agreed for other proposed PBS reform matters being delivered.

It resulted in widespread panic and anxiety as to the Government's intent and focus, and questions were raised in many circles as to the true objectives of the decision occurring in this way. It was felt the intent of the Australian government was to deliver a projected Budget surplus, and therefore the deferrals were part of short term fiscal planning. But the critical point is that short term deferrals are not the case – as Minister Roxon herself has conceded³

¹ The Hon Nicola Roxon MP – Minister for Health and Ageing: Media Release 25 February 2011

² COAG Reform Council Report on Performance against the National Healthcare Agreement. June 2011

. There is no timeline for how long a drug can be deferred from the point of completing a full regulatory submission process and being recommended to the Minister and Cabinet for listing, and there is no timeline on how long a drug recommendation can be waiting before Cabinet for consideration.

The Australian Medicines policy – of which the PBS arrangements are part, speak to a notion of transparency and timeliness for delivering drugs to Australians who need them. The announcement made in late February dismissed both considerations in the way it was articulated and defended, and as a result the government is seen to be unaccountable to obligations for ongoing final listing arrangements. The situation under these conditions is one of effectively backlogging medicine potentially ad infinitum.

The ongoing position is untenable as it also continues to display a disturbing disregard for the expert and independent mechanisms in place for evaluation and determination of cost effectiveness and clinical benefit for any drug submitted for consideration of PBS listing. The result is that when any medicine has been finally approved for listing since February 2011, it has really been medicine approved and judged by Cabinet members to be the next priority for Australian patients, a situation which is clearly inappropriate.

Firstly, because it is effectively casting aside a formal regulatory approval process that is considered to be a global benchmark for rigorous evaluation and assessment. Secondly because Cabinet is intervening to subjectively allow or disallow a medicine to come to public access, with no scientific or medical application determining in what order or time period. This seriously undermines faith in the system being an ongoing framework for people to rely on for bringing drugs to Australia, and does little to instill confidence for Australian patients waiting for those drugs to become available. At a broader political level it also undermines faith in the members of parliament who believe this is a suitable role for Cabinet to be playing in such a controversial and provocative context. The PBS process has always been accepted in a bipartisan spirit as an evidence-based process to effectively keep political considerations out of the business of determining access to life sustaining drugs and therapies.

Of growing concern to many of the patient groups and health consumer networks is the spectre of ongoing listing deferrals that affect availability of new medicines and drugs in Australia. The publicly declared position of Industry representatives that this decision undermines the pharmaceutical industry confidence in a stable regulatory and policy environment for business and investment ⁴ points to the future impact if there is no strategic interest from the drug companies to bring their products to Australian patients under the current arrangements. Several scenarios can eventuate in this situation - which are all unacceptable.

- Risk of return of competitive health lobbying across specific interests, including across patient groups trying to pursue specific treatments advocacy agendas outside of the approvals process, and across a divided and partisan political environment.
- Listing deferrals leading to pressure via public campaigns and media coverage rather than rigorous assessment and transparent evaluations to determine appropriate access.
- Fear mongering about equity and social inclusion principles between stakeholders and across community sectors in a highly pressured economic climate.

³ The Hon Nicola Roxon MP – Minister for Health and Ageing: Transcript of Doorstop 25 February 2011

⁴ ABC – The Drum; Glenn Milne; Drug deal a bitter pill for business. 12 April 2011

- Two class system of treatment affordability – private purchase becoming an option for some but beyond the capacity of many.
- Health outcomes being compromised as new developments in medicines and drug therapies are delayed or even lost from the Australian system altogether.
- Pharmaceutical industry responses become fragmented across patient population focus, driven by other market factors rather than commitment to a PBS listing.
- Other linked drug programs such as clinical trial investment and special access programs (for patients needing early access while waiting for drug listings), become smaller or even abandoned in the future.
- Drug pipeline planning for the registration and availability of medicines in Australia are reconsidered by global parent companies.

The PBS has been in place in Australia since 1948. It is a critical part of the Australian healthcare system and it is populated by drugs that by an overwhelming proportion go to those Australians living with life threatening and chronic illnesses. The scheme has a stated objective to allow Australians access to affordable and needed medicines to save their lives, improve their quality of life, and help insure that people with chronic illnesses can continue to work, participate and function in the community.

It is too important to be damaged by those who have made decisions to set aside the architecture by which it is shaped so as to effectively freeze the delivery of drugs, and it is too important to be used as a short term budgetary goal. There are numerous Australian government strategies and plans committing to the policies of keeping patients well, and keeping them out of hospital. The Australian government should continue to provide a scheme that delivers quality medicines to those who need them most, and support the mechanisms and process in place prior to February 2011 that will not undermine those goals.

NAPWA is the peak community based organisation in Australia representing the interests of people living with HIV/AIDS. It is governed and constituted solely by men and women living with HIV, across the country. It is a national not for profit association providing advocacy, policy, education and outreach for its membership organisations, and on behalf of all people living with HIV. NAPWA membership includes organisations for people living with HIV (PLHIV) in each state and territory and the following members and networks: the networks of Positive Heterosexuals; National Positive Women's Networks; and the Positive Aboriginal and Torres Strait Islander Network (PATSIIN).

NAPWA works across a range of clinical, health care and HIV-positive education initiatives to promote the highest quality standards of HIV treatment and support, and to facilitate appropriate clinical and social research into the impacts and progression of HIV. NAPWA is a founding member of the Australian Federation of Disability Organisations (AFDO), and a core member of the Consumers Health Forum (CHF).

NAPWA is funded by the Commonwealth Department of Health & Ageing to provide advocacy and policy advice to Government and other agencies on national issues affecting people with HIV, and is a national member of the Blood Borne Virus & STIs Subcommittee of the Australian Population Health Division Principal Committee (APHDPC). NAPWA is identified as a central partner in the National HIV/AIDS Strategy, and people living with HIV are considered a priority population in the Australian HIV response, as supported by the Australian government.