



**Submission to the Senate Finance and Public
Administration References Committee Inquiry
into the Government's administration of the
Pharmaceutical Benefits Scheme (PBS)**

July 2011

Introduction

The Mental Health Council of Australia (MHCA) is the peak, national non-government organisation representing and promoting the interests of the Australian mental health sector, committed to achieving better mental health for all Australians. The membership of the MHCA includes national organisations of mental health services, consumers, carers, special needs groups, clinical service providers, community and private mental health service providers, national research institutions and state/territory peak bodies.

The MHCA focus for this submission is upon the Cabinet's recent shift of their position to now be the decision-making body for approving all PBS listing. Previously, Cabinet would assume this authority for costs exceeding \$10 million (in the four-year period following listing), but for amounts less than this, they would generally accept recommendations from the Pharmaceuticals Benefits Advisory Committee (PBAC) for proposed listings that would cost less than \$10 million. This submission makes a number of suggestions to ensure that a high level of equity and accountability is maintained for the protection of all involved parties.

The Context

People living with mental illness constitute one of the most disadvantaged and marginalised groups in our community. They are overrepresented in homelessness and unemployment statistics, they experience poorer overall health outcomes when compared to other Australians, and when it comes to maintaining acceptable levels of mental health and wellbeing, they often report having to choose between paying for healthcare or meeting their daily needs.¹

Medicines play an important part in the maintenance and treatment of mental illness for Australians living with mental illness, and the PBS, established in 1948, is the foundation upon which equity in access to necessary medicines is ensured to all Australians, no matter what their personal circumstance or financial situation. Since its inception, the PBS has grown to subsidise a vast suite of medications for the treatment of many illnesses, including mental illness. Since 1953, listing medicines to the PBS has been overseen by the independent statutory body, the PBAC. PBAC members are tasked with considering the clinical effectiveness and cost effectiveness of medicines, and to provide a series of recommendations to the Minister for Health about which should be made available through the PBS.

Until recently, positive recommendations made by the PBAC that would cost the Government less than \$10 million per annum in the first four years of listing, were consistently approved by the Minister and listed to the PBS. For positive recommendations that cost more than \$10 million per annum in the first four years of listing, consideration by Cabinet was required. This process for listing medicines to the PBS is renowned across the world. It is widely considered transparent, accountable, independent and equitable, and has retained the confidence of the Australian public, and in particular health consumers, for over 50 years.

In February 2011 the decision was made for Cabinet to be the decision-making body for all PBS listing, regardless of cost. Since this change, Cabinet has deferred the listing of several new medicines, with the Government indicating that this was due to budget pressures.

While the Government is entitled to make such changes to the processes governing the listing of medications to the PBS, the MHCA holds a number of concerns in relation to these changes and how they will affect Australians living with mental illness, their carers and

¹ SANE Australia (2009). Money and mental illness. SANE Australia Research Bulletin 9.

families. We believe that the best policies and processes for governing the administration of PBS, including any recent changes, should demonstrate a commitment to each of the following five principles derived from the National Medicines Policy and the National Mental Health Strategy:

- Transparency
- Accountability
- Independence
- Equity
- Consumer-orientation

These principles are already present in much of the Commonwealth's health policy and procedure, and should be equally applied to the processes which govern the administration of the PBS. This submission has provided a response to the recent changes against the context of these five principles.

Transparency

Maintaining public confidence in the processes that govern PBS listings is important, and can only be achieved through process and transparency. Prior to February this year the Australian public could be confident in the knowledge that the PBAC had assessed the effectiveness of medicines prior to them being recommended to the Government for listing to the PBS. The PBAC processes were well understood, well-articulated and their decision-making reasoning was published in a comprehensive and timely fashion. Since the Government announced changes to the PBS listing process, the same levels of transparency in process and information dissemination have not been evident.

The MHCA supports the decision-making process by Government, or indeed any appointed body, as long as this is conducted in an open and transparent manner, similar to that demonstrated by the PBAC previously. The MHCA would support the development of a new reporting mechanism to safeguard the transparency of the PBS listing process.

Accountability

Accountability is integral to maintaining public confidence in the processes that govern PBS listings. A lack of explanation or information dissemination in relation to listing deferrals may result in questions regarding decision-making processes and reasoning, regardless of their soundness. For example, the decision to defer the PBS listing of a medicine to treat schizophrenia was based on the fact that an alternative, similar treatment for schizophrenia was already available on the PBS.^{2 3} Indeed, there are a myriad of medications available on the PBS to treat schizophrenia, including one that is administered in a similar fashion to the one deferred. The medicine that is already listed on the PBS is a different substance to the one deferred, and it is well understood that while one medication might work for one consumer, it will not necessarily work for another.

Accountability will require that the detailed reasoning underpinning Cabinet decisions is made available for public scrutiny. If Cabinet is going to continue to review all PBAC recommendations, the MHCA emphasises the importance of committing to similar levels of accountability that were previously expected and demonstrated by the PBAC.

² Minister for Health, Media Release: Erbitux and Other New Medicines Listed on the PBS. 21 June 2011

³ Minister for Finance and Deregulation. Transcript of Interview – 2GB with Alan Jones. 15 April 2011

Independence

Central to the PBS listing process prior to February this year was the principle of independence. The PBAC is an independent statutory body. Introducing a Cabinet review process may undermine the independence of these decisions. For example, different sections of the health and health consumer sector are funded to provide the best possible voice for their constituents at the coalface of policy and program development, and on occasion the success of one part of the health sector can come at the cost of others within the health and health consumer sector. While it is important to have each part of the sector advocating for the best outcomes for their constituency, decisions about PBS listings need to remain independent from the influence of the health and health consumer sector and other interested parties. Ensuring that Cabinet decisions consider the independent advice offered by the PBAC may go some way to alleviating concerns about independence.

Equity

A central tenet of Australia's health system is health equity - no matter what your personal circumstance, you will have the same access to quality affordable health care as everyone else. For people living with mental illness, health equity has historically been difficult to achieve. There are many reasons for the continuing health inequity experienced by people living with mental illness, including historical under resourcing of mental health services, the impact of mental illness on people's ability to work and pay the bills and the stigma associated with mental illness.

Introducing Cabinet review of all PBAC recommendations, rather than those that are costly, may also create unnecessary delays in PBS listing of medicines and limit access to essential medicines for consumers who cannot afford a private prescription. For a person with a mental illness, deferring the PBS listing of medicines recommended by the PBAC to treat mental illness will undoubtedly create additional barriers to treatment, possibly exacerbating their health inequities.

The PBAC itself may not be tasked with considering or addressing health inequities amongst Australians when assessing the merits of listing a medication to the PBS, but the Government is required to consider such things. Improving choice and convenience in medicines is but one way in which the health inequities experienced by people living with mental illness can be improved. Greater choice and convenience will also lead to improved adherence to the treatment regime and quality of life for mental health consumers, which in turn leads to fewer relapses, reduced ongoing healthcare costs, and increased education and employment participation.⁴

Consumer-orientation

When assessing any changes to the PBS listing process, the impact on consumers, carers and their families must be considered. The internal processes that govern PBAC decision-making provide for a consumer position on the committee, and the consideration of submissions from consumers and other members of the public. These same opportunities are not built-in to the Cabinet review process, nor were consumer and carer views sought before the Government took its decision to defer medicines listing and review all future PBAC recommendations. The MHCA strongly encourages the Government to consider the ways in which it can incorporate consumer and carer views and the impact of its decisions on

⁴ SANE Australia. Media Release: SANE Australia calls for PBS inclusion of Invega Sustenna. 29 April 2011

consumers in its decision-making processes, so as to best exemplify its commitment to consumer-oriented health policy.

Conclusion

The MHCA understands that the current fiscal environment puts additional pressure on the Commonwealth budget, and that the Cabinet is entitled to review, cut or defer PBS expenditure. At a minimum, the MHCA would like to see the Government evaluate its changes to the PBS listing process against the five principles of transparency, accountability, independence, equity and consumer-orientation, and amend its processes where deficits in relation to these principles are identified. To implement this level of rigor acts not only as good process but protects everyone involved, minimising the adverse risk of uncertainty and capriciousness. In summary, the MHCA recommends that the following priority areas need to be implemented as key components to any decision-making body in relation to PBS listing.

1. The listing process should incorporate the five principles derived from the National Medicines Policy and the National Mental Health Strategy.
2. Any decision-making process needs to be transparent and the reasoning behind any decision regarding deferring, listing or rejecting a drug should be available and challengeable.
3. A review process should be in place to ensure that existing, deferred and new drugs are considered and re-considered periodically.
4. Although the decisions regarding resource allocation may be made by Cabinet, these processes should not confuse or conflate clinical advice decisions with economic decisions.
5. Consumers and carers must be an integral part of the decision-making process at all levels.