



A submission on behalf of the Chronic Illness Alliance

To the

Senate Finance and Public Administration Committees
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The Government's administration of the Pharmaceutical Benefits Scheme (PBS)

The Chronic Illness Alliance undertakes to address the following terms of reference of this Inquiry:

- (a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee;
- (b) any consequences for patients of such deferrals;
- (g) the consultation process prior to a deferral;

Introduction

The Chronic Illness Alliance aims to build a better focus on the needs of people with chronic illnesses in health policy and health services. The Alliance represents 55 organisations working with people with a range of chronic illnesses across Australia. This submission is on behalf of all people with chronic illnesses, all of whom rely on the consistent supply of effective medicines through the Pharmaceutical Benefits Scheme. A list of Alliance members is attached.

Background

The National Medicines Policy was established in 1999 to produce better health outcomes for all Australians through the quality use of medicine (1). Central to the policy are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and,
- maintaining a responsible and viable medicines industry.

Under the National Medicines Policy the Pharmaceutical Benefits Scheme (PBS) forms the main vehicle for implementing and managing this policy process. The Pharmaceutical Benefits Advisory Committee (PBAC) receives applications for listing of medicines on the PBS and these are considered according to safety and effectiveness in comparison to existing medicines already available for the treatment of similar conditions. The Pharmaceutical Benefits Pricing Authority (PBPA) then considers the cost and price and recommends a suitable price at which the medicine is listed on the PBS. It has been noted that this is a lengthy and complex process.

The National Medicines Policy states that:

‘Each partner shares responsibility to various degrees for achieving each of these objectives and all partners need to consider these central objectives in any relevant initiatives.’

‘This Policy recognises the fundamental role consumers have in reaching these objectives, and there needs to be a commitment from all partners to ensuring consultation with consumer representatives when new arrangements are contemplated.’

The recent deferral by Federal Cabinet of the listing of medicines on the PBS suggests that these tenets of the policy have been eroded by this action.

In this submission The Chronic Illness Alliance amplifies the reasons such erosion will seriously disadvantage people with chronic illnesses.

Deferral of medicines by Federal Cabinet

The recent deferral of listing to the PBS of medicines erodes the partnership between stakeholders to ensure that there is timely access to effective medicines. The PBAC contains all stakeholders including representatives of the Dept of Health and Ageing, medical practitioners and medical researchers, pharmacists, epidemiologists and health economists.

It should be noted however, that the consumer voice is a relatively muted one, with only one consumer representative amongst seventeen other members. Further, this consumer representative no longer represents a broad constituency. Thus there was little or no avenue to consult with consumer representatives before this action was taken, even had this been a priority of the Federal Cabinet.

Where people with chronic illnesses are concerned the most important aspect of this deferral relates to shift in priority from timely access to affordable medicines to budgetary considerations. This becomes a form of cost-shifting to a small group of consumers whose medical conditions such as prostate cancer, Multiple Sclerosis and Cystic Fibrosis mean they are the ones who can least afford to bear the cost of that shift.

People with chronic illnesses rely on access to affordable medicines both in terms of staying alive and/or having a quality of life which allows them to contribute to the community either through employment or a voluntary capacity. The research undertaken by the Chronic Illness Alliance demonstrates how important access to affordable medicines is for all people with chronic illnesses. In 2003 the Alliance undertook a survey of people with chronic illnesses in regional Victoria on costs of chronic illnesses (see: <http://www.chronicillness.org.au/reports.htm#costs>) (2).

This survey showed that despite access to subsidised medicines through the PBS many households where there were chronic illnesses were spending large proportions of their household income on PBS medicines. The following summary demonstrates that people with chronic illnesses are not in a position to accept more cost-shifting in their lives:

The questionnaire survey results represent the experiences of 381 rural and regional households with at least one member with a chronic illness. The households comprised 1626 people, of whom 507 had chronic illnesses.

The results showed that households with chronic illnesses in rural and regional Victoria:

- **pay for their health needs regardless of income**
- **experience considerable poverty and financial distress**
- believe they are worse off under the new tax system
- benefit greatly from having concession cards if they use a large range of health and support services
- **spend more on Pharmaceutical Benefits Scheme and over-the-counter medications than any other health-related item**
- greatly value access to bulk-billing GPs
- need access to better information, and allied health and support services
- find the costs of travel, telephone and utilities onerous.

Additionally the survey found that families went without other essentials such as food, heating, family holidays and recreation and clothing in order to pay for essential medicines.

Similarly a report by Access Economics (2005) into the economic costs of multiple sclerosis in Australia found that when lost productive capacity and informal care were taken into account the costs of caring for someone with MS was estimated at \$37,333 per person with MS per year (3). At the same time

‘Pharmaceuticals for people with MS, mainly new generation interferons, are estimated to cost \$84.1m in 2005 (14% of total costs). These therapies have a strong evidence basis showing cost effectiveness in slowing progression and enhancing wellbeing and productivity for people with MS.’

The Chronic Illness Alliance continues to collect information from its members around a range of issues. The constant theme is that access to affordable treatments including medicines allows people with chronic illnesses to take advantage of those treatments. They can thus participate in the day to day activities that well people take for granted. An example of this comes from cystic fibrosis (CF)

Gillen et al writing in the American Journal of Respiratory and Critical Care as long ago as 1995 pointed out that in 1980 only 20% of those with CF lived longer than the age of 16. With advances in treatment this had risen to 36% by 1990 and there were increasing numbers of young people with CF in the US workforce (4).

Access to affordable medicines thus has its own budgetary advantages far beyond savings to the health budget and these should be taken into account.

The dangers of opening avenues for the manipulation of the political process by pharmaceutical companies

As an expert committee the PBAC has another important role. Acting independently of the political process it prevents manipulation of politicians and policy by pharmaceutical companies that want to have medicines listed on the PBS. Should Federal Cabinet undertake the role of deferral and consequently approval of medicines Cabinet members, political parties and backbenchers are likely to be more subject to lobbying and marketing tactics of pharmaceutical companies.

Such tactics are both sophisticated and subtle (5, 6). They include: data mining (where data are scrutinized for anything favorable to support PBS listing, the use of peer-review articles reporting favorable research which in some cases may have been ghost-written by employees of pharmaceutical companies, seeding trial (pseudo research to assess safety, efficacy and benefits of medicines that are in fact marketing exercises to persuade clinicians to either support a drug to be listed or to ensure it is more widely prescribed). Pharmaceutical companies have used seeding trials to market both Vioxx and Neurontin in recent years. Another form of manipulation is to call on desperate consumers and their families to lobby politicians for either listing on the PBS or for off-label use. These forms of manipulation are often hard to detect (for example the seeding trial for Neurontin in the US has taken 16 years to be uncovered and has been the subject of litigation (6).

The Chronic Illness Alliance argues that the process of listing medicines to the PBS must remain an evidence-based process which is separate to any political process. It is only by maintaining separation that people with chronic illnesses can be assured their needs are being met through an objective process.

There are other ways the Government could make savings and also benefit consumers

There are other ways to save on the costs of PBS medicines. The Chronic Illness Alliance notes the following discussion regarding the costs of generics in other countries such as New Zealand and Britain compared with Australian costs. The following article demonstrates this in relation to Lipitor (7)

'Australia pays more for medicines because the price is set by a regulation that prompts a price cut of just 16 per cent when a new, generic competitor enters the market, and then a 12-month price disclosure process that reveals what price pharmacists pay.'

Other countries such as Canada cut the price they pay by 75 per cent when a drug comes off patent, while New Zealand and The Netherlands run a tender system that delivers much cheaper medicines.

To contain the costs of the drug subsidy scheme, the Gillard government has this year delayed assistance for six new medicines that its expert advisory body wants subsidised.

The government says it cannot afford to pay for a cost-saving new schizophrenia medication, Invega Sustenna, a pain relief drug called Targin, a drug to prevent blood clots called Fragmin, a treatment for lung problems called Symbicort, an endometriosis treatment called Synarel and a medical use for Botox.

Professor Clarke says the government could easily afford subsidies for these and other drugs if it cut the price it pays for generics.

He says one way of doing so would be to move to a tender system such as the ones used in New Zealand or The Netherlands.’ Quoted from:

<http://www.theaustralian.com.au/news/nation/high-priced-generics-push-out-new-drugs/story-e6frg6nf-1226086728647>

Similarly Harvey et al look at the savings that could accrue to the PBS in the following case of ranibizumab or bevacizumab for neovascular macular degeneration (8).

Summary

- Access to affordable medicines has its own budgetary advantages including allowing people with chronic illnesses to access those medicines which improve their quality of life, often making it possible for them to access or remain in employment. This produces budgetary advantages to the whole Australian economy.
- The process of listing medicines to the PBS must remain an evidence-based process which is separate to any political process, thereby avoiding any manipulation by pharmaceutical companies. It is only by maintaining separation that people with chronic illnesses can be assured their needs are being met through an objective process.
- More effective means to make savings to the PBS with advantages to both Government budgets and consumers both in terms of savings and quality use of medicines should be explored.

References

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<http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-2>
- (2) Chronic Illness Alliance, The costs of chronic illness for rural and regional Victorians 2004 <http://www.chronicillness.org.au/reports.htm#costs>
- (3) Access Economics, Acting Positively: Strategic implications of the economic costs of multiple sclerosis in Australia 2005
- (4) Gillen M, Lanas D, Brown C, Velln E, Blanc P Work disability In adults with cystic fibrosis. American Journal of Respiratory and Critical Care Medicine 1995;152:15J-6
- (5) Washington H 2011 Flacking for big Pharma, The American Scholar
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- (6) Krumholz S, Egilman D & Ross J Study of Neurontin: Titrate to effect. Profile of a Safety (STEPS) trial. A narrative account of a Gabapentin seeding trial. Arch Intern Med 2011;171 (12): 1100-1107
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http://www.mja.com.au/public/issues/192_11_070610/cla11057_fm.html

Members of Chronic Illness Alliance

AIDS Housing Action Group
 Arthritis Victoria
 Asthma Victoria
 Australian Crohn's and Colitis Association
 Australian Leukodystrophy Support Group Inc.
 Bendigo Community Health Services
 beyondblue
 Brainlink
 Cancer Council of Victoria
 Cancer Voices NSW Inc
 Cardiomyopathy Association of Australia Ltd.
 Carers Victoria
 ChIPS
 Continence Foundation Australia
 Cystic Fibrosis SA Inc
 Cystic Fibrosis Victoria
 Diabetes Australia - Victoria
 Doutta Galla Community Health Service
 Epilepsy Foundation of Victoria
 Epilepsy Australia
 Frameworks for Health
 Frankston Community Health Service
 Genetic Support Network Victoria
 Haemophilia Foundation of Victoria
 Health Issues Centre
 Hepatitis C Victoria
 Huntington's Victoria
 Kidney Health Australia
 Knox Community Health Service
 The Leukaemia Foundation
 Life Goes On
 ME/CFS Society of Victoria
 Ménière's Support Group of Victoria
 Monashlink Community Health Service
 Multiple Sclerosis Society of Victoria/New South Wales
 Myeloma Foundation of Australia
 Ovarian Cancer Australia
 Paediatric Continence Association of Australia
 Parkinsons Victoria Inc
 PASS
 Peers Inspiring Peers
 People Living with HIV/AIDS Victoria
 Pharmacy Guild of Australia, Victorian Branch
 Polio Network
 Positive Women
 Prostate Cancer Foundation of Australia
 Royal District Nursing Service
 Scleroderma Victoria Inc
 Stroke Foundation (The National Stroke Foundation)
 Thalassaemia Society of Victoria
 Thyroid Australia
 The Type 1 Diabetes Network
 Victorian Aboriginal Community Controlled Health Organisation
 Victorian AIDS Council