Submission to the

Senate Finance & Public Administration Committees

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On behalf of Multiple Sclerosis Australia (MSA)

to

The Government's administration of the

Pharmaceutical Benefits Scheme (PBS)

MS Australia represents around 20,000 people in Australia who live with Multiple Sclerosis (MS) a majority of who depend on consistent supply of effective medications through the PBS. We are pleased to have the opportunity to make a submission to this inquiry, and can provide further information through written submission or presentation before the committee.

1. Multiple Sclerosis

Multiple sclerosis (MS) is a progressive, chronic disease of the central nervous system (brain and spinal cord). It is the most frequent neurological disease in young and middle-aged adults in developed countries and has a lifelong impact[1]. Because MS involves multiple areas of the central nervous system, it is characterised by a variable and complex range of symptoms, including visual disturbance, fatigue, pain, reduced mobility and coordination, cognitive impairment, and mood changes.[2] Average age at onset is between 20 and 40, and 75% of people with MS are women. Thus, MS tends to strike people in their most productive years. It affects ability to fulfil expected life roles at a stage when careers, relationships, and adult life in the community are consolidating, with resulting impact on work, family, and social life.[3].Thus, MS may result in profound biographical disruption.[4]

The typical course of MS is initially relapsing-remitting, with symptoms partially or completely disappearing during remissions. However, after about 10 years, the majority of people enter a secondary progressive phase and disability gradually accumulates. For a smaller group, the disease course is primary progressive, with ongoing worsening of the initial presentation.[5]

Importantly, the last decade has brought changes in medical management, with the introduction of disease-modifying drugs that reduce exacerbations in relapsing-remitting MS, resulting in less unpredictability in the early stages of the disease. [6]

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[1] Johnson, K.L., Yorkston, K. M., Klasner, E. R., Kuehn, C. M., Johnson, E., & Amtmann, D. (2004). The cost and benefits of employment: A qualitative study of experiences of persons with multiple sclerosis. *Archives of Physical Medicine and Rehabilitation*, *85*, 201-209.

[2] Polman, C. H., Thompson, A. J., Murray, T. J., & McDonald, W. I. (2001). *Multiple Sclerosis: The Guide to Treatment and Management* (5th ed.). New York: Demos

[3] Metz, L. (2003) The psychosocial consequences of multiple sclerosis. In W. I. McDonald & J. H. Nosworthy (Eds.), *Multiple Sclerosis 2* (pp. 329-339). Philadelphia, PA: Butterworth-Heinemann

[4] Reynolds, F, & Prior, S. (2003). "Sticking jewels in your life": Exploring women's strategies for negotiating an acceptable quality of life with multiple sclerosis. *Qualitative Health Research*, *13*, 1225-1251.

[5] Demetriou, M. (2005). Multiple sclerosis, genetics, and autoimmunity. In M. J. Olek (Ed.), *Multiple Sclerosis: Etiology, Diagnosis, and New Treatment Strategies* (pp. 103-112). Totowa, NJ: Humana Press.

[6] Calabresi, P. A. (2004). Diagnosis and management of multiple sclerosis. *American Family Physician*, *70*, 1935-1944.

As a group of people living with a debilitating chronic illness, it is essential that the medications required to treat symptoms and allow people to maintain as independent a life as possible are affordable. A large number of our constituents as many people with chronic illness develop co-morbid chronic illness (e.g. arthritis, diabetes amongst others) and become dependent on medications to make life liveable with these multiple conditions. A list of commonly used medications and supplements used to manage MS is in the appendix. The extent of this list and the high individual cost demonstrates the importance of access to medications to manage the disease. The key goal of clinical and pharmacological management of MS is to maintain a quality of life which allows them to contribute to the community either through employment or a voluntary capacity. Treatments coming down the pipeline that can improve people's function to enable continuing employment and regular participation in life are keenly watched by the MS community.

In a study into the costs of MS in Australia, Access Economics (2005) found that when lost productive capacity and informal care were taken into account the average cost of each person with MS was estimated at over $37,000 per year (2). At the same time

'Pharmaceuticals for people with MS, 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.'[7]

As new and better treatments are available it is important that there is a transparent process for them to be evaluated and brought to market to continue to enable Australians with MS available access to the best and most efficacious treatments. The Pharmaceutical Benefits Scheme provides a world class process for this to occur most of the time.

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2. The deferral of listing medicines on the PBS that have been recommended by the PBAC and its potential impacts

The PBS is a central part of Australia's health system and operates under the, National Medicines Policy, with is central objectives[8]:

- 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

A key feature of the PBS is that is has an evaluation process that is independent. This is central to keeping the PBS free from manipulation or lobbying by industry or political interests. There is substantial financial, political and health interest in the workings of the PBAC and it is essential that it remain independent.

MSA shares the Consumers Health Forum's concerns about the deferrals and the changed process for approval decisions to the Cabinet.

- Delays in access to essential medicines
- Lack of transparency in the new process
- Politicisation of PBS listing process
- Risk of extra costs and adverse health outcomes as a result of delays and/or refusals

The recent decision by the Australian Government to refer all PBAC recommendations to Cabinet for approval risk creating unnecessary delays, uncertainty for industry and unnecessary and divisive lobbying by disease groups. The PBAC evaluates new medications on the basis of cost and clinical effectiveness using highly rigorous processes and there currently no better evaluation method in the country. The new process appears one dimensional and lacks appropriateness because it has no visible evaluation methodology other than assessing one off budget impacts. MSA believes that the PBAC recommendations

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[8] http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policydoc~national-medicines-policy-2

under the $10 million threshold, the required cost impact can be managed at the ministerial level (as they have been) without crowding the Cabinet agenda with small amounts of necessary expenditure and creating avoidable angst and delays.

Where the budget impact is over $10m Cabinet has always had the final decision, and MSA does not have any issue with this policy continuing. MS immunomodulatory drugs have always fallen into this category, and the first MS oral medication was approved on this basis by Cabinet and announced for PBS subsidy on the 21st June 2011. This was a warmly welcomed decision by MS Australia and the MS community, and we believe this was the result of a good PBAC process and the Cabinet recognising the value proposition inherent in the PBAC recommendation.

It is hard to see any justification in Cabinet taking a different view on the recommendations of the other deferred medications, however the delay and uncertainty is costing money and delaying access to these options that are recognised as being effective.

MSA supports the submissions of the Consumer Health Forum and the Chronic Illness Alliance and their position that the process of listing medicines to the PBS must remain an evidence-based process which is separate to any non-expert political process.

In short, for people with MS, the PBS is a major aspect of ensuring that their health care needs are met. Consequently, MS Australia is concerned about this change in policy and the impact it will have on integrated health policy and continued affordable access to the best available treatments.

A major concern of people with MS and other health consumers is that there is no transparency around the new process. While MSA recognises that the budgetary decisions taken by Government are important and are the preserve of Government, they must always be taken on the basis of the best available evidence. Once the PBAC has evaluated the evidence and made a recommendation, there is nothing that a political process can add. The cost effectiveness arguments have been made alongside the health benefits that would accrue from making a particular treatment available.

Where people with MS are concerned the most important aspect of this deferral relates to budgetary considerations seeming to outweigh the established operations of the PBS evaluation system. People with MS already have very high health costs in addition to the currently subsidised treatments, and are very sensitive to the issues of cost and access.

With the course of the disease being so unpredictable, the use of medicines is a high priority to be able to try to influence its impact. As well as the main MS immunomodulatory treatments, people with MS use a range of other medications to manage daily symptoms, such as neuropathic pain, fatigue and constipation (as a side effect of other medications).

While the MS drugs have not been impacted by this deferral, it is the case that other treatments that assist in the management of the disease or that are needed to treat a co-morbid condition may be caught up in the deferral process.

Having the PBAC process to evaluate new treatments has proven itself to be a good way of dealing with the inevitable reality of improved technology, scientific progress and medical research. This progress will not stop, and in many cases cost will be a significant issue, but if cost effective health benefits can be proven, then it is counterproductive to hold these new treatments up on cost alone.

In the case of MS we have seen the first oral medication just listed, which adds a very useful string to the treatment bow, and there are more treatments in the pipeline. We rely on the PBAC and the TGA to ensure these are effective and safe as well as being accessible, but also would not like to see any unreasonable barriers put in the way of them being made available when these other criteria are satisfied.

People with chronic illnesses that are reliant on the health and welfare system are far more vulnerable to shifts in public policy than other Australians and have fewer options in being able to adapt to new arrangements – particularly if they have negative consequences (such as reduced access to supports, higher levels of compliance or higher costs).

Their lives are already compromised in terms of employment, community participation and overall quality of life, and decisions such as the deferrals are a visible reminder of their vulnerability.

While people with MS were not directly affected by the decision to defer approval of the group of medications, they have stated that they are concerned about what this may mean for the ongoing process to bring improved treatments to Australia.

3. Summary

MSA recognises the constant challenge for government to balance their expenditure priorities, however any decisions in the health area need to be informed by the best evidence. The PBS is such an important part of our health system that it impacts on many areas of the Australian community and a range of federal government portfolios other than Health, so delays in access to new medications are likely to have negative cost and human impacts in programs that could offset any short term budget savings achieved through deferral or refusal of PBS listings.

MSA supports a return to the pre-February 2011 arrangements for the evaluation, recommendation and listing of efficacious new treatments on the PBS. The deferral of PBAC recommendations introduces potential risks to PBS processes that the PBAC expressly exists to minimse.

4. For further contact:

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Appendix

The following tables show the large group of medications and other products used by people with MS to manage their disease, and the share of costs between Government and the consumer. A number of commonly used medications are not listed for MS on the PBS, and these are shown in table 2. The data is from 2004 from the Australian MS Longitudinal Study[9]

PBS Medications

Table 1 shows a range of PBS subsidised medications required to manage MS, and the cost distribution. As this group includes people who are working, the mean individual cost would include the non-concessional amounts for scripts as well as other costs. Gabapentin, the drug below with the highest mean individual cost as there is a high incidence of private scripts and internet buying of this drug by people in all income groups.

Table 1 PBS subsidised medications and cost distribution

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[9] Australian MS Longitudinal Study 2007 cost survey, Canberra Hospital ACT, MS Australia

	Respondents	% of Sample	Mean individual cost	Mean government cost
Interferon Beta-1B	286	27.6%	$170	$15,511
Interferon Beta-1A	184	17.8%	$335	$15,929
Baclofen	174	16.8%	$119	$949
Glatiramer Acetate	121	11.7%	$154	$14,145
Oxybutynin Hydrochloride	96	9.3%	$83	$132
Amitriptyline Hydrochloride	67	6.5%	$87	$81
Diazepam	66	6.4%	$84	$95
Sertraline Hydrochloride	55	5.3%	$118	$567
Carbamazepine	46	4.4%	$87	$325
Temazepam	45	4.3%	$80	$94
Paracetamol	44	4.3%	$38	$61
Prednisolone	41	4.0%	$299	$437
Venlafaxine Hydrochloride	31	3.0%	$235	$1,391
Codeine Phosphate with Paracetamol	29	2.8%	$225	$347
Citalopram Hydrobromide	26	2.5%	$221	$574
Amantadine Hydrochloride	24	2.3%	$55	$261
Sodium Valporate	24	2.3%	$125	$437
Nitrofurantoin	24	2.3%	$138	$233
Gabapentin	23	2.2%	$1,187	$3,681
Clonazepam	23	2.2%	$212	$152
Celecoxib	22	2.1%	$77	$497
Refecoxib	21	2.0%	$108	$484
Methotrexate	20	1.9%	$39	$79
Ibuprofen	18	1.7%	$47	$87
Paroxetine Hydrochloride	18	1.7%	$203	$456
Tramadol Hydrochloride	18	1.7%	$245	$880
Calcium	17	1.6%	$35	$64
Imipramine Hydrichloride	16	1.5%	$198	$110
Cephalexin	15	1.4%	$459	$216
Azathioprine	14	1.4%	$94	$467
Fluoxetine Hydrochloride	14	1.4%	$208	$460
Oxazepam	14	1.4%	$63	$50

Non PBS Medications

The AMSLS coded medications as being definitely for MS, maybe for MS and not MS. Only those that were definitely and maybe for MS were included in the list below. Unlike PBS subsidised medications, the ones listed below attract little or no government funding. The list includes some complementary medicines, dietary supplements and pain medications, all commonly used to manage symptoms and drug side effects.

Table 2 Non PBS Medications and cost distribution

	Respondents	% of Sample	Mean individual cost	Mean government cost
Vitamin and Mineral Supplements	699	67.5%	$206	$0
Analgesics	350	33.8%	$125	$0
Evening Primrose Oil	168	16.2%	$167	$0
Fish Oil | EPA | DHA	126	12.2%	$186	$0
Non-steroidal anti-inflammatory agents	115	11.1%	$177	$0
Skin Treatment [Ointment | Oil | Powder | Cream | Gel]	82	7.9%	$150	$0
Laxatives	72	7.0%	$151	$2
Cranberry Tablets	68	6.6%	$323	$6
Cranberry Juice	61	5.9%	$808	$0
Analgesics [combinations]	54	5.2%	$203	$0
Analgesics | Cardiac	49	4.7%	$85	$0
Flaxseed Oil	45	4.3%	$178	$0
Cod Liver Oil	44	4.3%	$78	$0
Ginko Biloba	31	3.0%	$215	$0
Enemas	30	2.9%	$151	$250
Immune Support Formula	19	1.8%	$439	$0
Dressing	18	1.7%	$107	$10
Anti-inflammatory Pain Relief Topical	15	1.4%	$133	$0
Sleep Aid	14	1.4%	$169	$0
Selenium	13	1.3%	$93	$0
Glucosamine	13	1.3%	$231	$0
Garlic	11	1.1%	$56	$0
Antacids	11	1.1%	$119	$0
Food Supplement	10	1.0%	$996	$0
Antiseptic Liquid	10	1.0%	$30	$30