5 July 2012

PBS Post-Market
Department of Health and Ageing
MDP 900
GPO Box 9848
CANBERRA ACT 2601
Via email to: PBSpostmarket@health.gov.au

Dear Sir/Madam

I am writing in reference to the call for submissions to the Review of Pharmaceutical Benefits Scheme anti-dementia drugs to treat Alzheimer's disease announced on 28 May 2012.

Medicines Australia is the peak organisation representing the research-based pharmaceutical industry in Australia. Our members comprise over 80% of the prescription medicines market and play an integral role in delivering better health outcomes for Australians through the discovery and bringing to market of new and innovative medicines. Medicines Australia represents sponsors of all four products being considered in the review.

Medicines Australia welcomes the opportunity to provide comments on the post-marketing review recommended by the Pharmaceutical Benefits Advisory Committee. Medicines Australia continues to fully support initiatives to ensure that the medicines are prescribed, dispensed and used in a responsible, appropriate and ethical manner. Furthermore, Medicines Australia and its members support the long standing Government commitment to subsidising patient access to medicines via the Pharmaceutical Benefits Scheme (PBS) within the pillars of the National Medicines Policy. To this end, Medicines Australia provides comments to support the evidence-based review of medicines in the post-market setting. We also recognise the number of reviews on medicines currently underway in Australia and the need for a common set of principles to underpin all reviews to ensure all stakeholders can adequately engage in the process.

Medicines Australia makes two recommendations for the review:

- A framework should be adopted to outline the process for the review of medicines in a post-market setting, including for the review of anti-dementia drugs; and
- Existing pricing policy must be considered when conducting cost-effectiveness analysis of products across formularies to appropriately inform equity of funding decisions.

<u>Recommended Framework for reviewing medicines in a post-market environment</u>

Medicines Australia supports ongoing post-market review processes and recognises the investigation of the PBS listed anti-dementia drugs on this premise.

Reviews of PBS listed medicines was initiated as part of the 2005 Federal Budget, where $2.5M was allocated to allow the PBAC to conduct cost-effectiveness reviews of already PBS listed medicines[1]. However, at the time information and guidance as to how these cost effectiveness reviews were to be conducted was limited to general commentary around selection, process and

[1] http://www.health.gov.au/internet/budget/Publishing.nsf/Content/Australian-Government-2005-06-Portfolio-Budget-Statements/$FILE/outcome2.pdf

outcome. Over recent years a number of reviews have been conducted, with different approaches, timelines and across a number of therapeutic areas. The announcement in the 2011Federal Budget of additional funds further signals an ongoing commitment to the post-market surveillance of PBS listed medicines.

Medicines Australia understands that each review will examine aspects idiosyncratic to each treatment area. Nevertheless, we believe that all the stakeholders would benefit from a clear process framework for the review of anti-dementia drugs. Medicines Australia has advocated a template framework which should be adopted for all PBAC reviews (**Table 1**). In particular, for the anti-dementia drug review, Medicines Australia is unsure that the outlined process is sufficient for stakeholders to adequately engage in the process and to appropriately address the Terms of Reference.

The proposed template framework will provide clear benefits to all stakeholders as it will afford all parties the opportunity to deliver the most appropriate information to decision makers and hence be most informative to Government. The framework is sufficiently flexible to allow reviews to be conducted efficiently and informatively. Given the short timeframe for stakeholder feedback, it is unlikely that sponsors can provide comprehensive information to inform a robust economic assessment.

Table 1: Proposed Review Framework

The announcement that a review is scheduled to take place should trigger an invitation to affected stakeholder(s) immediately to discuss the following:

Framework	Guiding Principles
1. Timing	• Discuss and reach agreement on a review timeframe. Noting that timing for each review would be case dependent and determined in part by data availability and review circumstance.
2. Work plan	• Discuss and reach agreement on review work plan*, e.g. - Terms of Reference for the investigation - what information/models may be informative for outcomes and recommendations?
3. Data input	• Discuss and reach agreement on appropriate data sources to be used in the review*, e.g. - what level of evidence is required? - what local databases are valid?
4. Stakeholder input	• Discuss value of stakeholder input and at what point in the review process this should be sought and considered. Consider timing for stakeholders to prepare contributions
5. Outcome	• Detail initial thoughts as to potential PBS implications associated with review outcomes.
6. Transparency	• Discuss and reach agreement on a potential transparency plan post finalisation of the review.

* Sponsors, PBAC, the Department and other stakeholders may need to meet again on multiple occasions to agree or finalise specific work plans &/or data inputs relevant to the review at hand.

Informed cost-effectiveness analysis

A cost-effectiveness analysis for the anti-dementia drugs in the review is rendered particularly complex by the market conditions for which each product is currently listed on the PBS. Two of the products, donepezil and rivastigmine, are currently listed in the F1 formulary, while the other products, galantamine and memantine are listed in F2.

Medicines Australia has worked with the Government through PBS reforms and subsequently the Memorandum of Understanding (MoU) to create a sustainable reimbursement structure for medicines listed on the PBS. Following the 2007 reforms the PBS was split into two distinct formularies:

- F1 for innovative products listed on value-based health technology assessments. The MoU extends this to ensure pricing policy stability for products while under patent; and
- F2 for products subject to market competition. This is chiefly to ensure that the Government can make ongoing price adjustments, via price disclosure, to reflect prices they are being sold at in the marketplace

Maintaining clear distinctions between the two formularies enables both sustainability for Government procurement of medicines and provides a pathway for timely subsidy of innovative medicines for patients. The Government committed to this via Clause 5 of the Memorandum of Understanding.

> *The Commonwealth confirms its commitment to the principles and architecture of PBS Reform and, in particular, to maintain in accordance with the National Health Act 1953:*
>
> - *the separation of drugs between the F1 and F2 formularies and combination drug list; and*
> - *the different price setting and maintenance mechanisms which underpin the formularies.*

The PBS price of memantine took a statutory price reduction 1 April 2010 and has been subject to price disclosure arrangements, yet has not been subject to a further reduction. Galantamine took a statutory price reduction on 1 August 2010, and has subsequently reduced by a further 17.55% price reduction as part of the first main cycle of expanded and accelerated price disclosure. This shows the ongoing savings being delivered by PBS reforms and the MoU.

An informed cost-effectiveness analysis should account for these occurrences. Medicines Australia is confident that the PBAC advice will reflect appropriate clinical and economic utilisation of anti-dementia medicines. We expect that the advice and final decisions by the Minister will incorporate and respect the F1/F2 market conditions of the reviewed products and the structure of PBS reforms.

Should you have any questions about this submission, please do not hesitate to contact Medicines Australia's Reimbursement Strategies Manager, Jim Crompton on (02) 6122 8560 or by email at jim.crompton@medicinesaustralia.com.au.

Yours sincerely,

Dr Brendan Shaw
Chief Executive