15 November 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 Post-Market Review of Products Used in the Management of Diabetes announced in October 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 products being considered in the extant review.

As an industry organisation, Medicines Australia is not in a position to respond specifically to the terms of reference highlighted in the stage one call for submissions. However, Medicines Australia would like to draw the Department's attention to concerns with both the procedures for and the nature of post-market reviews.

Medicines Australia makes *three* recommendations for the review:

1. That the Department recognises and acknowledges feedback from industry on the uncertainty, unpredictability and ad hoc nature of the review process;
2. That the Department adopts an appropriate framework for the process of reviewing medicines in a post-market setting, including for the review of PBAC-approved / PBS-listed diabetes medicines; *and*
3. That the Department agrees to engage with Medicines Australia to better understand industry's perception of issues with the nature of reviews to date.

This review illustrates the procedural issues that have characterised post-market reviews to date; for example, the process and timeline for submissions to stage two of this review, pertaining to diabetes medicines, is unclear. Therefore, we take this opportunity to reiterate industry's request that the Department adopt an appropriate and predictable framework with guiding principles for the initiation and conduct of reviews of Pharmaceutical Benefits Scheme (PBS)-listed/ Pharmaceutical Benefits Advisory Committee (PBAC)-approved medicines.

Medicines Australia continues to support initiatives to ensure that medicines are prescribed, dispensed and used in a responsible, appropriate and ethical manner. We also recognise and accept that Government has the right and responsibility to review medicines that it reimburses through the PBS. However, our principal concern

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with reviews of PBS-listed/ PBAC-recommended medicines to date, is that they have been managed in an ad hoc manner with significant uncertainty regarding the initiation, terms of reference, conduct and process of reviews.

This uncertainty in process inhibits meaningful engagement with stakeholders, including affected pharmaceutical companies, thus limiting the value of any findings. This lack of clarity has an impact on business activity, Australia's reputation as a stable, predictable market and jeopardises Australian patients' access to the medicines they need over the long term.

We have maintained this position over the past few years and have reiterated our concerns directly with the Department of Health and Ageing, including at Access to Medicines Working Group (AMWG) meetings, MA-PBAC meetings and most recently in Medicines Australia's submission to the "Review of Pharmaceutical Benefits Scheme anti-dementia drugs to treat Alzheimer's disease", dated 5 July 2012.

Noting the Department's preference for contextual feedback from stakeholders, Medicines Australia is consolidating formal feedback from affected sponsors on their experiences with reviews to their PBAC-approved / PBS-listed medicines between 2006 -2012, including reviews of medicines used in type 2 diabetes mellitus. We intend to share this feedback with the Department in the coming months to ensure a robust and informed dialogue on Medicines Australia's recommendations:

Recommended Framework for reviewing medicines in a post-market environment

Medicines Australia understands that reviews, by necessity, will examine aspects idiosyncratic to each treatment area. Nevertheless, all stakeholders are entitled to procedural fairness, including a consistent and transparent process framework for the review of anti-diabetes medicines and all other medicines under review. Medicines Australia has previously advocated for the adoption of a template framework for all post-market reviews (**Table 1**).

In particular for the current diabetes review, Medicines Australia is not confident that the process outlined on www.pbs.gov.au is adequate for stakeholders to effectively engage in the process and to appropriately address the Terms of Reference:

- Some sponsors of affected products were not notified directly by the Department, and the indirect means of notification was inadequate to reach major stakeholders;
- The information for the review fails to outline a timeline that sponsors can work towards; the deadline for submissions to stage one of the review had to be extended, and as far as Medicines Australia is aware there has been no consultation on reasonable dates to meet stage two; and
- It is unclear who is conducting and is responsible for the outcomes of the review, i.e. PBAC, the Department, "Expert Advisory Group", evaluation unit, etc.

An appropriate and predictable framework will provide clear benefits to 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. Medicines Australia believes the proposed framework should initiate a joint effort to establish a mutually agreed framework that will meet the needs of the Department and all stakeholders.

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Table 1: Proposed Framework for Discussion

The decision to conduct a review should trigger an announcement detailing the nature of the review and an invitation directly to affected stakeholder(s)* 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 expectations 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, Medicines Australia, PBAC, the Department, others as identified. ** 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.	

Medicines Australia looks forward to working with the Department to resolve the procedural issues identified in this submission.

Additionally, Medicines Australia would like to raise concerns as to the nature of post-market reviews. Medicines Australia asserts that the primary basis for reviews should be improving clinical understanding and to ensure usage of treatments are in line with accepted PBAC recommendations.

Further, the industry expects that, when receiving and acting on the advice of the PBAC, the Government should act in accordance with existing PBS policy, the National Medicines Policy and the Memorandum of Understanding with Medicines Australia (MOU).

Medicines Australia will continue to liaise with our members to gather and consolidate their feedback on the procedural issues and uncertainties faced in the reviews conducted in the last few years. We would welcome the opportunity to discuss this industry feedback and the establishment of an agreed framework and guiding principles for the initiation and conduct of reviews with the Department.

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Should you have any questions about this submission, please do not hesitate to contact me on (02) 6122 8525 or by email at elizabeth.desomer@medicinesaustralia.com.au. In the alternative, you may wish to contact Ms Kristin Trace, Policy Manager, on (02) 6122 8507 or by email at kristin.trace@medicinesaustralia.com.au.

Kind Regards,

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