2 April 2013

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 Pharmaceutical Benefits Scheme Medicines Used to Treat Asthma in Children* announced in February 2013.

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. Medicines Australia's members include sponsors who supply the medicines under review in the *Post-Market Review of Pharmaceutical Benefits Scheme Medicines Used to Treat Asthma in Children* (herein, 'Children's Asthma Review').

As a peak industry organisation, Medicines Australia is not in a position to respond specifically to the terms of reference highlighted in the call for submissions. However, as representatives of many affected companies of this review and post-market reviews in general, Medicines Australia would like to draw the Department's attention to industry's previous submissions and concerns regarding the deficient processes and policy implications of post-market reviews.

Medicines Australia makes *three* recommendations for the review:

1. That the Department agrees to engage with Medicines Australia and other stakeholders to better understand the problems with reviews to date.
2. That the Department acknowledges and addresses the feedback from industry on the deficient processes and the policy implications of post market reviews; and
3. That the Department adopts an appropriate and transparent framework for the process of conducting post market reviews, including for the Children's Asthma Review.

Process concerns

Despite some limited additional information added to the Department's website in the past few months, post-market reviews continue to be run with deficient processes and inadequate transparency. Uncertainty in process inhibits meaningful engagement with stakeholders, including affected pharmaceutical companies, and limits 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.

The Children's Asthma Review is illustrative of the procedural issues that have characterised post-market reviews to date, for example:

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- **The Department's guidelines for reviews are inadequate, and are not being followed in all instances.**
    - The Department's website indicates that sponsors will be notified one to two weeks before a review is publicly announced. However, some sponsors were notified only one or two business days prior to the public announcement of the Children's Asthma Review. Medicines Australia is disappointed that the Department did not follow their own guidelines for reviews, (no matter how insufficient we believe those guidelines to be).
    - While some history on the triggers for the Children's Asthma Review has been provided on the review webpage, there is no rationale for how the medicines under review were selected.
    - Further, the general review guidelines/framework provided on the Department's general reviews webpage fail to adequately address several important aspects, including:
        - the process undertaken to identify stakeholders;
        - the methods of notification of stakeholders, including for those less likely to regularly interact with the Department on PBS issues;
        - the health technology assessment (HTA) standards and guidelines which are applied;
        - detailed information on the opportunities for sponsors and other stakeholders to provide evidence and other information at multiple points throughout the review (e.g. in the ordinary PBAC submission process, sponsors are aware of opportunities for pre-subcommittee submissions, pre-PBAC submissions, opportunity to seek independent review, and other touch points);
        - the guidelines/framework for the post-review process including consideration and implementation of any recommendations (the most egregious example of procedural deficiencies in previous reviews have been in the post-review process, for example, sponsors were afforded less than ten business days to consider the commercial implications and respond to a major reimbursement request in the Review of PBS anti-dementia drugs to treat Alzheimer's Disease,)
- **Engagement with stakeholders is inadequate.**
    - As Medicines Australia is aware, Children's Asthma Review stakeholders were not given the opportunity to provide feedback on the most appropriate review work plan, terms of reference, timeframes or evidence likely to be valuable in the review. Sponsors, as experts on their products and the keepers and developers of much of the data relevant to post market reviews, should be consulted as soon as a review is initiated for their input. For example, a sponsor may be able to provide advice on a realistic timeframe for providing (or generating) necessary data.
    - The quality and rigor of post-market reviews must be as high as ordinary PBAC and listing processes, for which sponsors invest several months developing submissions with adequate evidence and modelling. Earlier engagement with sponsors in the Children's Asthma Review would likely have indicated that six-weeks' is inadequate to develop and lodge a comprehensive submission in line with the scope, quality and detail expected from the PBAC.
- **Roles and responsibilities are not transparent.**
    - No information has been provided on the general reviews webpage or on the Children's Asthma Review webpage as to who will be receiving and

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reviewing submissions lodged by stakeholders. This is inappropriate. Meaningful engagement in the review process can only occur if stakeholders understand what is at stake, who is the reviewer and how their submissions will be assessed.

- It is noted on the Children's Asthma Review webpage that an advisory group will be convened yet no information has been provided on the membership of this group or whether this action has been progressed. Furthermore, no information has been provided as to how members were/will be selected or what expertise the members have or will be expected to have. This lack of information upfront gives the appearance that the process is either ad hoc and unpredictable or that the Department intends for this information to be hidden from public view.
- It is noted that 'an external contractor has been engaged to conduct a literature search and evaluation of more recent clinical research' on the medicines under review, but no information has been provided on who will conduct the other aspects of the review, for example the 'further analysis of PBS data and review of international guidelines for asthma'.

The examples of uncertainty and inadequate processes for the Children's Asthma Review must not be ignored. For reviews addressing medicines issues such as safety, effectiveness, cost effectiveness, utilisation, medication management and quality use of medicines, the outcomes may affect patient access, restrictions and the reimbursed prices for medicines. These outcomes may have stakeholder implications as significant as the original PBS-listing process, and the procedural framework and level of stakeholder input of post-market reviews should be as thorough as with all other PBAC and listing processes.

Medicines Australia reiterates industry's request that the Department adopt an appropriate, predictable and transparent framework with guiding principles for the initiation and conduct of reviews of Pharmaceutical Benefits Scheme (PBS)-listed/ Pharmaceutical Benefits Advisory Committee (PBAC)-approved medicines.

Policy concerns

Medicines Australia continues to support initiatives to ensure that medicines are prescribed, dispensed and used in a responsible, appropriate and ethical manner.

To ensure alignment with existing policy, the Government should consider and report on the implications of reviews and reviews outcomes in relation to the National Medicines Policy. Medicines Australia recommends that this reporting commence with the Children's Asthma Review.

When acting on the advice of the PBAC regarding a post-market review, including the Children's Asthma review, the Government should:

- Act in accordance with existing PBS policy and the National Medicines Policy;
- Utilise the most appropriate policy levers (e.g. price cuts to medicines may deliver savings to Government, but are unlikely to address findings of inappropriate utilisation);
- Administer outcomes with sufficient time for sponsors and other stakeholders to consider their options and respond;
- Advise affected stakeholders of their options, which must include a mechanism for independent review and/or dispute resolution.

Moreover, the Government should be mindful that if due care is not taken post-market reviews outcomes may misalign and therefore jeopardise current policies put in place to ensure the long-term sustainability of the PBS. Where the cost of the medicines under review is considered, Medicines Australia recommends that the Minister seek Departmental advice on how the market dynamics have affected the basis for relative product comparisons. This will ensure that pricing relativity between formularies is not re-established and that post-market reviews outcomes do not undermine PBS Reforms.

Conclusion

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. Alongside this, the Government's clear commitment to ensure alignment of the post-market reviews program with existing policy will give stakeholders greater confidence in the program.

Medicines Australia has been consistent in its position on post-market reviews and has reiterated our concerns at a number of opportunities directly with the Department of Health and Ageing, including at Access to Medicines Working Group (AMWG) meetings, MA-PBAC meetings and in submissions to post market reviews including the 'Review of Pharmaceutical Benefits Scheme anti-dementia drugs to treat Alzheimer's disease' and the 'Review of Products Used in the Management of Diabetes' (stage 1).

Medicines Australia has collected examples from members of the procedural deficiencies in previous post-market reviews. Further, Medicines Australia has developed what it considers the key elements needing to be addressed in the Department's post-market reviews framework and guidelines, and refined previous work offered to the Department. We would welcome the opportunity to work with the Department to address industry's concerns and proposed solutions.

Should you have any questions about this submission, please do not hesitate to contact [redacted]

Kind Regards,

Elizabeth de Somer
Director, Health Policy and Research
Medicines Australia