

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

16 June 2014

Dear Sir/Madam

Re: Terms of Reference for the Post-market Review of Authority Required PBS Listings

Medicines Australia welcomes the opportunity to address the Terms of Reference for the Post-market Review of Authority Required PBS Listings (herein, 'the review') 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 Authority Required PBS listed medicines.

Medicines Australia acknowledges that the TOR for the review, as listed on the Pharmaceutical Benefits Scheme (PBS) website, 27 May 2014 are:

1. Review the criteria used by the Pharmaceutical Benefits Advisory Committee (PBAC) to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS.
2. Systematically review the current Authority Required listings according to the proposed criteria to ensure this is applied consistently to all PBS Authority listed medicines.¹

Medicines Australia would like to acknowledge that the review has two parts to be applied to several 'tranches' of medicines. TOR one being a review of the appropriateness of the policy setting and criteria for designating a PBS listed medicine as Authority required. The second TOR relates to the application of this policy and criteria for currently listed Authority required medicines.

Medicines Australia acknowledges that the perceived intent of the review aligns with the Governments stated commitment to reduce unnecessary red tape for the government, business and the community. The review could also prove beneficial to prescribers and patients, by reducing the red tape currently associated with prescribing and dispensing some medicines.

Medicines Australia notes that the current requirements for prescribers for the two categories of authority medicine are:

1. **Authority required** medicines require telephone or written approval from Medicare Australia or DVA prior to prescribing.

¹ Post-market Review of Authority Required PBS Listings <http://www.pbs.gov.au/info/reviews/authority-required-listings> accessed on 12/06/2014

2. **Authority required (STREAMLINED)** medicines do not require telephone or written approval from Medicare Australia or DVA prior to prescribing. Streamlined authority medicines are identified in the Schedule with the heading Authority required (STREAMLINED) and a predetermined, four-digit streamlined authority code for each restriction.²

Should an Authority or Streamlined Authority not be required a PBS listed medicine may be prescribed under a Restricted or General benefit, which has significantly less regulatory burden for the prescriber.

Specific comments on the Terms of reference:

1. Review the criteria used by the Pharmaceutical Benefits Advisory Committee (PBAC) to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS.

Medicines Australia has a number of comments regarding the TOR mentioned above:

- The current criteria used by the PBAC to determine if a medicine should require an authority has, thus far, not been disclosed as part of the public consultation process. This criteria may be familiar to most sponsors, clinicians and prescribers, however not all stakeholders will be as familiar as these groups.
 - Medicines Australia recommends the release of the current criteria on the review webpage, as it would assist stakeholders to provide relevant feedback as part of the public consultation on the TOR, and call for submissions when these are made.
- Medicines Australia acknowledges that “the objective of the Review is to improve patient safety and care by reducing red tape and administrative burden for health professionals”. Medicines Australia recommends this be explicitly stated in the TOR. For example;
 - Review the criteria used by the Pharmaceutical Benefits Advisory Committee (PBAC) to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS, with the objective of improving patient safety and care by reducing red tape and administrative burden for health professionals.
- Further information on the process for reviewing the current criteria is needed. For example
 - it is unclear what process will be undertaken by the PBAC for reviewing the criteria, and under what basis changes will be assessed.
 - it is unclear if stakeholders will have an opportunity to provide general comment upon the ‘proposed’ changes to criteria, as opposed to providing comment on the appropriateness of the ‘proposed’ criteria as they relate to each tranche of medicines named on the review webpage.
 - It is unclear how and/or whether potential changes to the Authority required criteria will affect the criteria for restricted and general benefit.
- Medicines Australia recommends that the review consider any unintended consequences, such as potential for over utilisation and/or inappropriate prescribing.
- As the terms of reference do not include reference to a review of the cost-effectiveness of Authority required medicines, it would be unacceptable for the recommendations of this review to include pricing measures.

² Medicare website, Authority Prescriptions, <http://www.medicareaustralia.gov.au/provider/pbs/education/pbs-and-you-manual/authority-prescriptions.jsp> accessed on 14/06/14

2. Systematically review the current Authority Required listings according to the proposed criteria to ensure this is applied consistently to all PBS Authority listed medicines.

Medicines Australia has a number of comments regarding the ToR mentioned above:

- Medicines Australia believes that it is appropriate to review medicines in order of highest regulatory burden currently placed on prescribers. i.e those Authorities which represent the greatest number of phone authority requests, or represent the most complex form-completion to gain access to a drug for a patient.
- This ToR refers to the 'proposed' criteria but there is no explicit mention of proposed criteria being generated, nor is there information on the Departments intention to provide stakeholders with an opportunity to provide comment on the proposed criteria prior to its finalisation.
 - Medicines Australia recommends that stakeholders and sponsors are provided an opportunity to provide comment on the 'proposed' criteria prior to the criteria being applied to currently Authority Required PBS listed medicines.
- It is unclear how medicines with a positive PBAC recommendation and awaiting listing, or are currently before the PBAC will be affected if they fall into the first three tranches of medicines. Will the listing of these medicines be delayed if they fall into one of the tranche of medicines identified on the reviews webpage?
- Medicines Australia and the industry would welcome any additional information on other medicines which will be scrutinised by this review.

Medicines Australia's position and procedural concerns regarding post-market reviews

Medicines Australia continues to support initiatives to ensure that medicines are prescribed, dispensed and used in a responsible, appropriate and ethical manner. Medicines Australia continues to maintain that any post-market review should have a clear focus on Quality Use of Medicines, not on arbitrary pricing measures. Medicines Australia supports the stated intent of this review focussed on *improving patient safety and care by reducing red tape and administrative burden for health professionals.*³

Medicines Australia acknowledges that important steps have been taken towards improving the process of reviews, in addition to working towards producing an appropriate framework for their initiation and conduct. It is encouraging that further discussion between the industry and the Government on post-market reviews has been prioritised under the auspices of the Access to Medicines Working Group (AMWG). Medicines Australia recommends that the ongoing process to resolve outstanding areas of misalignment through the AMWG should be progressed before any new reviews are commenced.

Medicines Australia recommends that process improvements should be integrated into this review. Stakeholders and sponsors in previous post-market reviews have expressed concern at the short timeframe afforded to stakeholders and sponsors to respond to the review report. Prior notice of the timing of the consultation phase on the review report would allow the allocation of the necessary resources to respond to the review report.

³ PBS website, Post-market Review of Authority Required PBS Listings, <http://www.pbs.gov.au/info/reviews/authority-required-listings> accessed on 12/06/2014

We propose that the Department of Health and Medicines Australia reach agreement on the time that should be provided, and the length of response necessary, to make a meaningful comment on draft reports for ongoing reviews. For example, a time of at least four weeks (aligning to a consistent and suitable time in the PBAC calendar), should allow for substantive comments to be submitted on the review report. Affected stakeholders should be allowed up to 10 pages to respond to the review report.

Furthermore when acting on the advice of the PBAC regarding a post-market review, including the Post-market Review of Authority Required PBS Listings, the Government should:

- Act in accordance with existing PBS policy and the National Medicines Policy;
- Utilise the most appropriate policy levers (noting that price cuts to medicines are unlikely to address findings of inappropriate prescribing/utilisation);
- Consider the administration of outcomes with sufficient time allocated for sponsors and other stakeholders to consider their options and respond;
- Advise affected stakeholders of all the options available to them, including a mechanism for independent review or dispute resolution.

Conclusion

Medicines Australia supports initiatives to reduce the administrative burden and red tape on prescribers and dispensers of PBS listed medicines, which is the stated aim of this review. Medicines Australia looks forward to continuing to work with the Department of Health to provide sponsors and stakeholders with an appropriate, predictable and transparent framework for the initiation and conduct of post market reviews.

Should you have any questions about this submission or wish to discuss further, please contact me on [REDACTED], or by email at [REDACTED]

Kind regards

Elizabeth de Somer
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Medicines Australia