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

8 October 2014

Dear Sir/Madam

RE: Public Consultation on Authority Required Medicines for the Post-market Review of Authority Required PBS Listings

Medicines Australia welcomes the opportunity to provide a submission to 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 many Sponsors who supply Authority Required PBS listed medicines. Medicines Australia is not in a position to address each and every medicine under the scope of the review. Medicines Australia has encouraged all of its members who are sponsors of, or with an interest in, the medicines being considered in the review to provide a detailed submission.

General comments

Medicines Australia is concerned that the call for public submissions on the first tranche of medicines in this review has occurred in the absence of reviewing any agreed criteria or consultation on any proposed criteria for the current range of Authorities, including both full and Streamlined Authorities; complex, written or telephone applications. In the absence of information on the criteria being prepared, or the process for the Pharmaceutical Benefits Advisory Committee (PBAC) reviewing the criteria, Medicines Australia members and other stakeholders are unable to make an informed submission to the review. Medicines Australia understands that this concern is shared by other stakeholders outside the Medicines Australia membership.

Medicines Australia acknowledges that the objective of the review, *improving patient safety and care by reducing red tape and administrative burden for health professionals,"*[1] aligns with the Government's broader stated commitment to reduce unnecessary red tape for the Government, business and the community. Medicines Australia supports measures to improve patient care and safety and hopes that, by reducing the red tape currently associated with

[1] 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

prescribing and dispensing some medicines (via the Authority process), the review will prove beneficial for prescribers, patients and industry.

Medicines Australia members welcome the appointment of industry and other stakeholder representatives to the review reference group. Appropriate consultation and representation on the associated reference groups is an important factor for the post-market review process. Having an appropriate cross section of representatives should ensure that all aspects concerning the use of Authorities will be taken into consideration throughout the review. Given the breadth of stakeholders involved in this complex area, Medicines Australia encourages transparency of the reference group decision making so as to provide stakeholders with confidence in the ongoing review process.

Medicines Australia acknowledges that the Terms of Reference (ToR) for the review have changed since the PBAC considered the draft ToR at the July 2014 meeting:

1. Review the criteria used by the PBAC to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS including the advantages and disadvantages of an Authority Required or Authority Required (Streamlined) listing.
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.
3. Use the review to explore how to best use available secondary health data sources to provide information on the utilisation of Authority Required and/or Authority Required (Streamlined) PBS items.

Specific comments related to these ToR are outlined below.

Specific comments on the finalised Terms of Reference:

1. Review the criteria used by the PBAC to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS including the advantages and disadvantages of an Authority Required or Authority Required (Streamlined) listing.

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

- Neither the updated proposed criteria, or the criteria that was previously used by the PBAC to determine if a medicine should require an Authority, has been disclosed as part of the public consultation process.
  - Medicines Australia notes there is limited information regarding the Authority listing in the Guidelines for preparing submissions to the PBAC. However, this is not explicitly mentioned in the review page.
  - Medicines Australia recommends the release of the current/previous criteria and the proposed criteria on the review webpage. The availability of this information (endorsed by the Department / PBAC) is necessary to assist stakeholders to provide relevant feedback as part of the public consultation on each tranche during the review.
- Medicines Australia called for further information to be made public on the process for reviewing the current criteria in its submission to the ToR. Medicines Australia notes that much uncertainty remains in the process for this review, and there is limited visibility of the

role of the PBAC vs the role of the reference group on the review webpage. For example, as raised in the previous submission to the ToR:
  - It is unclear what process will be undertaken by the PBAC for reviewing the criteria, and on what basis changes will be assessed.
  - Based on the information outlined on the original review webpage Medicines Australia called for, and was of the understanding that, there would be general consultation on the proposed criteria developed by the reference group or PBAC, prior to a call for submission on each tranche of medicines. This does not appear to have occurred.
  - It is unclear how and/or whether potential changes to the Authority Required criteria will affect the criteria for restricted and general benefit listings, i.e., whether there will be any 'flow-on' effect.
- In the absence of the proposed criteria, Medicines Australia considers that the most appropriate criteria for assessing the need for an Authority should be commensurate with the primary aim of the review being to improve patient safety and care. As such, the initial criteria should be:
  - safety concerns;
  - monitoring and managing utilisation uncertainty;
  - Quality Use of Medicines (QUM); and
  - patient access;
- In addition to the above criteria focussing on the patient, Medicines Australia acknowledges the need for ensuring the drug is prescribed to the patients for whom the PBAC has made a positive recommendation. As such, an additional criterion for considering an Authority should account for:
  - the risk of potential leakage, particularly when the drug has a wider TGA indication than the PBS restriction or the PBS restriction requires evidence of meeting certain criteria for prescribing.
- It is important to take into account other factors that may relate to some of the concerns which would be addressed by an Authority such as:
  - risk share arrangements (RSAs) that may be in place with the manufacturer for a particular medicine. Any recommendations must ensure that changing the Authority will not unintentionally compromise a RSA.
  - administrative burden for prescribers and Medicare is not disproportionate to the concern being addressed by the Authority.
- It is prudent to ensure that the review covers the requirement and criteria for written Authorities. Consistent with the deregulation theme of this review, it is necessary to ensure that opportunities for reducing red tape, including assessing opportunities for paperless, electronic written Authorities.

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 reiterates that in the absence of any defined proposed criteria, it is not possible for stakeholders and sponsors to provide a constructive submission to this stage of the review. Despite this, Medicines Australia has several overarching comments which address this specific ToR:

- Medicines Australia recommends that the review consider any unintended consequences, such as the potential for over utilisation and/or inappropriate prescribing when assessing and making recommendations for each tranche of medicines.
- In addition to this, when reviewing each tranche of medicines the review must take into account any risk share arrangements (RSAs) that may be in place with the manufacturer for a particular medicine. Any recommendations must ensure that changing the Authority will not unintentionally compromise a RSA. If indeed such an impact is realised, i.e., if a change to the Authority Listing impacts an RSA, the Sponsor should be given the option to renegotiate the RSA.
- As the ToRs 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.

3. Use the review to explore how to best use available secondary health data sources to provide information on the utilisation of Authority Required and/or Authority Required (Streamlined) PBS items.

Medicines Australia notes that there is limited information available on the review website to properly establish what the review will consider to be primary or secondary health data sources. Medicines Australia welcomes further guidance on which secondary health data sources will be considered informative for the PBAC, and further opportunity to provide informed input to this ToR.

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 acknowledges that important steps have been taken towards improving the post-market review process, in addition to working towards producing an appropriate framework for their initiation and conduct through the Access to Medicines Working Group (AMWG). Medicines Australia is confident that the proposed framework and guidance document will bring more predictability and transparency to the Government's post-market review programme. Until such time as this guidance/framework document is published, Medicines Australia believes it is inappropriate to commence any new post-market reviews.

Medicines Australia acknowledges that process improvements have been integrated into this review, including longer timeframes for the development of submissions. However, when acting on the advice of the PBAC following a post-market review, 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 positions and respond;
- Advise affected stakeholders of all the options available to them, including a mechanism for independent review or dispute resolution.

Medicines Australia considers that other ongoing procedural and policy concerns with the post-market review programme and framework are currently being adequately addressed through the AMWG.

Conclusion

Medicines Australia supports initiatives to improve patient care and safety by reducing 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 (02) 6122 8500, or by email at Elizabeth.desomer@medicinesaustralia.com.au

Yours sincerely,

Elizabeth de Somer

Director, Policy and Advocacy

Medicines Australia