

**POST-MARKET REVIEW OF
AUTHORITY REQUIRED PHARMACEUTICAL
BENEFITS SCHEME LISTINGS**

Submission on Terms of Reference

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Introduction

Bayer Australia Ltd (herein Bayer) appreciates the opportunity to comment on the terms of reference of the Post-Market Review of Authority Required Pharmaceutical Benefits Scheme (PBS) Listings. This document considers the proposed terms of reference, including the process for collation of different authorities into tranches, as outlined on the PBS website¹.

Bayer understands that the main objective of the review is to improve patient safety and care by reducing red tape and administrative burden for health professionals¹. As such, Bayer supports this initiative and considers that forthcoming measures designed to simplify access to PBS listed medicines, whilst maintaining consistency with quality use of medicines principles, would be a welcome outcome of the review.

It is noted that there may be several reasons for a medicine or medicinal form to be considered for restricted benefit or authority required status as noted in the PBAC Guidelines², however the importance of monitoring specific items may diminish over time. Bayer suggests that significant time savings may be achieved by reducing the administrative workload associated with telephone approvals through greater use of Authority Required (Streamlined) listings where appropriate. Alternatively, in cases where the need for prior approval is considered vital, other efficiency measures may be possible, for example reduction of the complexity of paper PBS authority application forms which are currently required in several therapeutic areas to gain access to PBS listed drugs, or by leveraging greater use of technology within the process.

Bayer notes that one of the key drivers for establishing the review was the 2013 Review of Funding Arrangements For Chemotherapy Services, where it was identified that:

“Authority Required listings caused significant regulatory burden to prescribing medical oncologists”¹.

Indeed, one of the key findings of that review was that:

“Beyond funding, efficiency benefits could be achieved by reducing the complexity and administrative burden associated with chemotherapy reimbursement on the PBS”³.

Bayer is pleased that this initiative has been expanded to include all Authority Required listings and Bayer encourages the Department to consult with clinical experts in each therapeutic area to ensure that the daily burden associated with the current approval process and potential impacts on patient care are understood.

¹ Department of Health (2014). Post-market Review of Authority Required PBS Listings. <http://www.pbs.gov.au/info/reviews/authority-required-listings> accessed 03-Jun-2014.

² PBAC (2013). Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.4). <http://www.pbac.pbs.gov.au/content/information/printable-files/pbacg-book.pdf> accessed 03-Jun-2014.

³ Department of Health (2013a). Review of Funding Arrangements for Chemotherapy Services. <http://www.health.gov.au/chemo-review> accessed 03-Jun-2014.

Proposed Terms of Reference

The proposed terms of reference for the review are presented in Text Box 1.

Text Box 1: 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.
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.

Source: Department of Health (2014). Post-market Review of Authority Required PBS Listings. <http://www.pbs.gov.au/info/reviews/authority-required-listings> accessed 03-Jun-2014.

Bayer supports the use of criteria which ensure that restrictions appropriately reflect the level of monitoring required to manage the quality use of medicines and would welcome the publication of the criteria once these are finalised. In regard to the proposed terms, Bayer submits the following requests:

- That the review of criteria described in term 1 is expanded to include the criteria for “Restricted” listings in addition to “Authority Required” and “Authority Required (Streamlined)” listings, for the purposes of transparency of the criteria.
- That any potential changes to existing processes resulting from the review are communicated to sponsors in advance, with a timeline for implementation of changes that allows sponsors time to communicate with prescribers in regard to process changes as applicable to specific products.

Proposed Tranches

The proposed tranches for the review are presented in Text Box 2.

Text Box 2: Tranches

1. The PBS listings with the highest regulatory burden include drugs for the treatment of many types of cancer, multiple sclerosis, rheumatoid arthritis and other arthritis medicines. Therefore, these will be included in the first tranche of medicines to be reviewed in time for consideration by the PBAC at its November 2014 meeting.
2. The second tranche of drugs to have their authority status reviewed will include treatments for eye conditions and psychiatric conditions and cardiovascular disease, and will be prepared in time for consideration by the PBAC at the March 2015 meeting.
3. The third tranche, to be presented to PBAC at the July 2015 meeting, will include all remaining drugs not covered in their first two tranches as well as medicines used in palliative care.

Source: Department of Health (2014). Post-market Review of Authority Required PBS Listings. <http://www.pbs.gov.au/info/reviews/authority-required-listings> accessed 03-Jun-2014.

Bayer welcomes the review of all current Authority Required listings and acknowledges the size of the task involved and therefore understands the need to prioritise the review. Bayer accepts the methodology indicated for the prioritisation, namely that the authorities that create the greatest regulatory burden are targeted first, defined as 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 patient⁴.

In regard to the proposed tranches, Bayer submits the following request:

⁴ Department of Health (2014). Post-market Review of Authority Required PBS Listings. <http://www.pbs.gov.au/info/reviews/authority-required-listings> accessed 03-Jun-2014.

- That sponsors be notified of details of the specific authorities to be included in each tranche to avoid ambiguity, for example drugs listed for multiple indications.

Conclusion

Bayer supports the quality use of medicines and believes that Authority Required (Streamlined) listings provide a preferred solution where monitoring of drug use is required, but with reduced administrative burden.

It is noted that the review of the streamlined authority initiative published in 2009⁵ found that the majority of medicines showed no changes on historical trends⁵ and subsequently the streamlined authority system has been extended to further medicines that initially required a phone authority. Within that report, it is stated that:

“The AMA reported that feedback from prescribers was highly positive and indicated that the initiative has been a welcome and effective ‘red-tape cutting’ measure for prescribers.”⁵

In closing, Bayer supports the objective of the review and would be pleased to collaborate with the Department to discuss these topics further. Bayer would welcome measures arising from this review that reduce the administrative burden for prescribers and allow them more time to devote to patient care. Bayer would also appreciate communication throughout the process of the review.

⁵ Streamlined Authority Monitoring Group (2009). Streamlined Authority Initiative Review. <http://www.pbs.gov.au/reviews/streamlined-authorities/streamlined-authorities-12-month-review-2009.pdf> accessed 03-Jun-2014.