

A SUBMISSION IN RESPONSE TO A CALL FOR PUBLIC SUBMISSIONS ON THE POST MARKET REVIEW OF AUTHORITY REQUIRED PBS LISTINGS

The terms of reference relating to this review are as follows:

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.

In this submission I wish to address some of the effects the introduction of Authority Required (Streamlined) (ARS) has had on the utilisation of some PBS listed medications.

The introduction of the ARS listings has reduced administrative burdens on prescribers and pharmacists, however this has occurred at the expense of a greater increase in the utilisation of those ARS listed medications through the PBS.

If this review results in a greater number of items moving from 'Authority Required' listings to ARS listings I believe this will result in an increase in the number of items funded under the listings beyond the expected usage at the time of listing.

I refer to a recent report prepared by the Drug Utilisation Subcommittee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) entitled "**The use of antipsychotics in the middle aged**". This report was compiled by DUSC by the DUSC secretariat from two examinations of utilisation of antipsychotics in Australia considered by DUSC in February and June 2013. It has been recently more broadly published and I note that some of its findings have now been reported in the general popular press eg Brisbane's Courier Mail on 7 June 2014.

I consider that this report - although examining use of a small range of medications – ie typical and atypical antipsychotics – provides a window into the effects of the ARS system that has now been in use under the PBS/RPBS for some years.

The ARS is a popular system that reduces administrative burdens for prescribers and pharmacists. I understand that this 'streamlined' authority listing arose in response to a previous government's commitment to reduce 'red-tape' across a range of stakeholder-government interactions at a Commonwealth level.

Though the ARS listing has been a popular move with stakeholders it appears not to have provided the desired outcome from the government's perspective – ie reduce an administrative burden whilst maintaining integrity of access to and funding of a range of medications which are usually either relatively new to the market place or expensive or in many cases both.

I would like now to quote from the abovementioned report to illustrate the point that medications being prescribed and funded under ARS listings are being funded outside the specific PBS 'authority required' indications.

From page 20 of the report under discussion:

"The analysis shows that at least 155,630 adults within the 20-59 year age bracket were taking an antipsychotic in 2012. This equates to 1.24% of the Australian population for this age group. The numbers of people treated with antipsychotics is considerable higher than expected from estimates of the age prevalence of schizophrenia and bipolar disorder....Overall the numbers using antipsychotics lends weight to use in conditions other than schizophrenia and bipolar disorder in people aged between 20 and 60."

From page 21:

Quetiapine use has grown steadily since listing and now exceeds that of olanzapine in adults 20-59 years. In particular the use of the 25mg strength of quetiapine was higher than expected in the study.

As this strength is sub-therapeutic for the treatment of schizophrenia, BPD, GAD and major depression (the latter two not being PBS listed) this may indicate some 'off-label' uses such as insomnia where reported doses range from 25 to 200mg"

Also from page 21:

There is growing evidence to support the off-label use of antipsychotics to augment antidepressant therapy in patients with antidepressant refractory depression. The study shows co-administration of an antipsychotic with an antidepressant becomes more common with older age and may indicate some use in depression (perhaps co-morbid with anxiety and/or insomnia).

From page 22:

'However, the fact of considerable prescribing for reasons other than those subsidised by the Government on the PBS is evident, it difficult to quantify with a high level of confidence without more detailed studies'.

From page 23:

'It is a concern that as use in new indications rises there is often no corresponding incentive or obligation for sponsors or other parties to present the efficacy data to the regulators and the comparative effectiveness data to the payers'

This report raised a number of matters which highlighted the ineffectiveness of the ARS system to contain usage of these medications to the PBS listed indications. The only recommendation arising from the report was to reduce the number of repeats on one item from 2 to zero. This change will realistically have little effect on the totality of concerns raised by the report.

Conclusion

This DUSC report recognises a significant level of use for atypical antipsychotic medications in the treatment of other indications that are not supported by the PBS listings. This of course is reflected in an increase in the cost of these items - a cost not meant to be borne by the Government/public.

I consider that this report also provides evidence for the deficiencies in the ARS listing system that is now part and parcel of the PBS.

In undertaking of this review I humbly ask that the reviewers consider the negative impacts –as highlighted here – the streamlined authority system is having on increased usage and costs of medications and to re-think the value of this automatic system of prescribing new and/or high cost medications at the taxpayers expense.

Other methods (including increasing dependence on Government-sponsor partnerships and agreements, use of pharmacists in an authority approval process) should be examined that can reduce 'red-tape' but at the same time contain costs and usage within pre-determined indications.

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