



Drug Utilisation Sub-Committee Outcome Statement 3–4 October 2013

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 79th meeting on 3–4 October 2013.

DUSC is a national focus of excellence in collecting, analysing and interpreting data on the utilisation of medicines in Australia for use by the PBAC. Review of the utilisation of medicines is an essential management tool in facilitating the objectives of the National Medicines Policy.

Submissions to the PBAC

DUSC noted that 30 major submissions had been received for the November 2013 meeting of PBAC. DUSC provided detailed advice to the PBAC on projected usage and financial cost for major submissions where there is high cost, uncertain utilisation, first medicine in class or quality use of medicines concerns. The agenda for the November 2013 PBAC meeting can be found at <http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/agenda/pdf/pbac-meeting-agenda-nov-2013-v2.0.pdf>

Utilisation of PBS Listed Medicines

DUSC regularly examines utilisation of PBS items when there is at least 12 months of prescription data available and where DUSC or the PBAC has highlighted items of interest. When an analysis of utilisation is to be undertaken sponsors are notified, provided with a copy of the report and an opportunity to comment prior to the DUSC meeting.

Full restrictions for PBS listed medicines are available in the PBS Schedule (www.pbs.gov.au)

DUSC reviewed the utilisation of the following PBS medicines/groups of medicines in October 2013:

Botulinum toxin type A for axillary hyperhidrosis

Utilisation of botulinum toxin for axillary hyperhidrosis was lower than expected for the first year of PBS listing. DUSC considered that the following factors may have contributed to the lower use:

- an overestimation of the number of eligible patients;
- an overestimation of the uptake rate; or
- a shortage of registered botulinum toxin prescribers; as prescribers of botulinum toxin need to be registered through the Department of Human Services (Medicare) and meet certain training requirements.

Utilisation of PBS listed botulinum toxin for hyperhidrosis increased rapidly in the period 6–12 months after listing; slowing in the period 12–18 months after listing. DUSC considered that this could be primarily attributed to the number of patients initiating on botulinum toxin in the first year of listing, rather than continuing patients. DUSC recommended a subsequent analysis to look at the number of new patients and whether the characteristics of registered botulinum toxin prescribers have changed over time, once 2–3 years of data post-listing is available.

DUSC requested that the report be provided to the PBAC for information and prepared for publication on www.pbs.gov.au, with inclusion of information on the number and characteristics of registered botulinum toxin prescribers.

Magnesium aspartate for the treatment of hypomagnesaemia or chronic renal disease in the Aboriginal and Torres Strait Islander population

DUSC noted that the utilisation of magnesium aspartate for Aboriginal and Torres Strait Islanders was lower than expected in the first year of PBS listing. DUSC considered that use outside of the indication is unlikely. DUSC suggested that PBAC could consider whether an Authority Required (STREAMLINED) listing may be more appropriate.

DUSC requested that the report be provided to the PBAC and prepared for publication on www.pbs.gov.au.

Antifungals for systemic use

PBAC requested DUSC examine the utilisation of antifungals for systemic use.

During the period January 2008 to December 2012, utilisation of antifungal medicines increased. DUSC considered that this increasing use reflects a larger number of immunocompromised patients in the community.

DUSC requested that the report be provided to the PBAC for information and prepared for publication on www.pbs.gov.au.

Imatinib for the adjuvant treatment of gastrointestinal stromal tumour (GIST)

In the first year of listing, the number of patients treated with imatinib was higher than expected. DUSC considered that this could be due to an underestimation of the prevalent population. However, the number of prescriptions was lower than expected. DUSC considered that this was partly due to grandfathered patients transferring from non-PBS subsidised imatinib to PBS subsidised imatinib for part of their 12 months of therapy, thereby adding to the patient number but receiving fewer PBS prescriptions.

DUSC recommended another utilisation analysis of imatinib 24 months after the extension to listing to permit three years of treatment is implemented.

DUSC requested that the report be provided to the PBAC and prepared for publication on www.pbs.gov.au.

Medicines used for multiple myeloma: thalidomide, lenalidomide and bortezomib

DUSC requested an analysis of medicines used for multiple myeloma since a number of new medicines in different lines of therapy have been listed on the PBS in this therapeutic area over recent years.

DUSC noted there was a general trend towards higher than predicted utilisation and that this was likely to be due to the improving life expectancy of patients with multiple myeloma.

There was a dip in thalidomide Authority Approvals in 2010. DUSC considered this may be due to patients changing from thalidomide treatment to lenalidomide. DUSC requested additional data to see if changes in utilisation of lenalidomide also occurred in that period.

DUSC was of the view that risk share arrangements are vital for this therapeutic area to manage Government expenditure and considered that the findings of the report should inform future risk sharing agreements.

DUSC noted that future use of new multiple myeloma medicines could be underestimated if older epidemiological data that has not captured improving survival is used to develop estimates

of use. DUSC suggested that PBAC consider this in assessing any future submissions and requested that the report be provided to PBAC.

Indacaterol for chronic obstructive pulmonary disease (COPD)

DUSC noted that the utilisation of indacaterol was lower than predicted at the time of the submission.

DUSC noted that a significant amount of co-administration of respiratory medicines is occurring. DUSC considered that the co-administration of multiple long-acting beta agonist products is a significant quality use of medicines issue.

DUSC requested that the report be provided to the PBAC for information and that the quality use of medicines issues with indacaterol should be published in a peer reviewed journal.

Budesonide with eformoterol for chronic obstructive pulmonary disease (COPD)

In the first year of the extension to PBS listing, the utilisation of budesonide with eformoterol 400/12 in COPD appeared to be substantially higher than predicted in the submission. DUSC suggested that this might be related to an increasing awareness and diagnosis of COPD and the arrival of new agents to the COPD market.

There was a trend towards more initiations in winter compared to summer months. DUSC considered that this may indicate some use of the product outside of use for COPD, for example respiratory tract infections and cough.

DUSC requested that the report be provided to the PBAC for information and that the quality use of medicines issues identified in the analysis should be published in a peer reviewed journal.

Osteoporosis

This analysis was undertaken to improve the understanding of current trends in management of osteoporosis.

Since 2007, utilisation of osteoporosis medicines has attained a plateau. DUSC noted that use of the injectables (denosumab and zoledronic acid) has increased market share with respect to other osteoporosis treatments. DUSC noted the convenience of injectable over oral bisphosphonates in some settings, including residential aged care, and noted the need for vigilant monitoring of adverse effects in at risk groups such as the elderly.

DUSC noted that 57% of use of the oral bisphosphonates is now in combination products which contain calcium and cholecalciferol, and considered that there is a risk of over-supplementation with calcium. DUSC suggested that PBAC could consider moving the listings of single component bisphosphonates, including zoledronic acid, from Authority Required (STREAMLINED) listings to Restricted Benefit listings in order to encourage prescribing of single agents.

DUSC requested that the report be provided to the PBAC for information and prepared for publication in a peer reviewed journal.

Upcoming Utilisation Analysis of PBS Listed Medicines

Utilisation of the following medicines and therapeutic areas have been selected for consideration at future DUSC meetings.

Predicted versus Actual Utilisation Analysis

- Aprepitant

Analysis of multiple medicines in a treatment area

- Chronic myeloid leukaemia (CML)
 - DUSC suggested a review of dasatinib, nilotinib and imatinib for CML.
- Iron chelation therapies
 - PBAC requested that DUSC review iron chelation therapies.
- Denosumab and zoledronic acid for bone metastases.

An outcome statement will be available following each meeting of DUSC. For further information, please contact the DUSC Secretariat at DUSC@health.gov.au.

Professor Geoff McColl
Chair
Drug Utilisation Sub-Committee