



Drug Utilisation Sub-Committee Outcome Statement 29-30 September 2016

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 88th meeting on 29-30 September 2016.

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 34 major submissions had been received for the November 2016 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 2016 PBAC meeting can be found on the [PBS website](#).

Utilisation of PBS Listed Medicines

DUSC regularly examines utilisation of PBS items when there is at least 24 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. All reports, Sponsor comments and DUSC consideration of the reports are subsequently provided to the PBAC.

Full restrictions for PBS listed medicines are available in the [PBS Schedule](#).

DUSC reviewed the utilisation of the following PBS medicines/groups of medicines in September 2016:

Antifungals

In the 2015-16 financial year, 91,874 people received systemic antifungal medicines on the PBS. There were 203,228 prescriptions supplied at cost of \$35,564,069. Terbinafine and griseofulvin were the most widely used medicines with over 30,000 people supplied each of the medicines.

The number of fluconazole, itraconazole and posaconazole prescriptions has increased over time. The number of voriconazole prescriptions decreased after peaking in 2012 and its use has been lower than expected.

There was a sharp increase in the use of fluconazole from 1 April 2016 coinciding with the PBS listing changing from Authority Required (STREAMLINED) to a Restricted Benefit. DUSC requested that the use of fluconazole be monitored closely to see if the increase continues.

The DUSC requested that the report be provided to the PBAC.

Antipsychotics including a 24 month predicted versus actual analysis of quetiapine 25 mg

Previous reports¹ from DUSC raised concern about the utilisation of PBS listed antipsychotics for non-subsidised and off-label indications such as sedation. Trends of inappropriate prescribing were most evident for quetiapine 25 mg tablets where there were high and growing numbers of prescriptions despite this strength not generally being considered to be a therapeutic dose to treat the PBS subsidised indications of schizophrenia and bipolar disorder.

In response to this concern the PBAC recommended that the number of repeats of 25mg quetiapine be reduced from five to zero. This listing was considered to be sufficient for dose titration in bipolar disease and schizophrenia, and would encourage regular prescriber review for patients treated for non-subsidised indications.

DUSC found that the intervention to change the listing of the 25 mg strength to allow no repeats from 1 January 2014 was effective in supporting its intended use as a titrating dose for PBS listed indications and reducing inappropriate use. There were 136,000 fewer prescriptions of quetiapine 25mg dispensed through the PBS in 2015 compared with 2013.

While the use of quetiapine 25 mg had decreased, vigilance is still needed to encourage the appropriate use antipsychotics as off-label prescribing is still evident. Limited data are available to weigh up the benefits and harms of off-label prescribing of antipsychotics.

Age-adjusted rates of antipsychotic prescribing increased with age, particularly in people aged 80 years and over. The widespread use of antipsychotics in the elderly was considered to remain an issue.

The DUSC requested that the report be provided to the PBAC; noting that the change of quetiapine 25mg listing to allow no repeats has resulted in a large decline in the number of quetiapine prescriptions dispensed through the PBS.

Mifepristone and misoprostol for termination of pregnancy

Mifepristone and misoprostol were PBS listed for the termination of an intra-uterine pregnancy on 1 August 2013. When recommending this listing, the PBAC considered that medical termination of pregnancy with mifepristone and misoprostol allows a choice for women who have decided to undergo a termination, and its availability through the PBS was considered unlikely to result in an increase in overall terminations of pregnancy.

Data available to date suggests the introduction of mifepristone and misoprostol on the PBS has not increased the number of terminations of pregnancy in Australia per year.

The proportion of terminations of pregnancy undertaken by the medical method has been lower than predicted. Factors contributing to this may include that the proportion of women choosing medical rather than surgical termination may have been overestimated, jurisdictional laws in some states and medical indemnity insurance requirements may pose a barrier, there

¹ June 2013 Outcome Statement: <http://www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos>;
February and June 2013 DUSC reports: <http://www.pbs.gov.au/info/industry/listing/participants/public-release-docs/dusc-public-release-documents-by-medicine>

are a low number of certified prescribers, and there is some private prescribing not captured in the PBS dataset.

The DUSC requested that the report be provided to the PBAC for information.

Osteoporosis

In 2015, close to 500,000 patients were treated with osteoporosis medicines through the PBS. Prior to 2015, the rate of treatment with osteoporosis medicines was in decline despite reports of increasing prevalence. DUSC noted that this may be attributed to safety concerns with the use of some of the medicines but also considered the clinical practice of taking drug “holidays” from the bisphosphonates may be a factor in the lower treatment rates.

Approximately half of all people starting osteoporosis therapy for the first time in 2015 were prescribed denosumab and a large number of people already on treatment with other medicines switched to denosumab. The higher than expected uptake of denosumab may relate to patient and clinician preference for a medicine given as a six-monthly subcutaneous injection. Although denosumab appears to be well tolerated and is viewed by clinicians to be comparatively safe, DUSC considered that ongoing vigilance and education is required to minimise the risk of coadministration of oral osteoporosis medicines with the injectable medicines, to recognise and manage adverse events of denosumab, and to understand the risk of vertebral fractures occurring after denosumab discontinuation.

The DUSC requested that the report be provided to the PBAC.

Rifaximin for prevention of hepatic encephalopathy

In the period from 1 December 2013 to 31 March 2016, 2,892 people were supplied at least one PBS/RPBS prescription for rifaximin. The number of patients supplied rifaximin was higher than predicted in both the first and second years of listing.

The number of prescriptions per patient per year was lower than estimated. This may indicate poor adherence or intermittent use.

The DUSC requested that the report be provided to the PBAC.

Testosterone

The report sought to determine the impact of the PBS restriction changes to testosterone that occurred on 1 April 2015. In the year after the restriction change, there was a 20% reduction in the number of people supplied PBS-subsidised testosterone and a 60% reduction in the number of people starting subsidised testosterone for the first time compared to the year before.

The most extensive restriction changes were for people aged 40 years or older who had androgen deficiency not caused by a pituitary or testicular disorder. In this group, there was an 86% reduction in patients starting subsidised testosterone for the first time.

DUSC noted a number of responses were received from stakeholders, including clinical groups. DUSC requested that the report and stakeholder responses be provided to the PBAC.

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

- Everolimus for metastatic hormone receptor positive, HER2 negative breast cancer in combination with exemestane
- Iron, as ferric carboxymaltose
- Tobramycin inhalation for pseudomonas aeruginosa infection in cystic fibrosis patients

Analysis of multiple medicines in a treatment area

- Medicines for the treatment of ulcerative colitis, including predicted versus actual use of biologics for acute and maintenance treatment.

Other matters

DUSC considered a report on PBS medicines prescribed by authorised dental practitioners. This report provided information on the regulation of prescribing by dentists, medicines available on the PBS for dental use, and an analysis of the utilisation of PBS medicines prescribed by dental practitioners.

Dental practitioners prescribed a very small range of medicines. DUSC noted that 20 medicines accounted for 99% of all dental prescriptions.

DUSC requested that the report be provided to the Australian Dental Association to assist with dentist education and to the Australian Commission on Safety and Quality in Health Care to inform their work on antimicrobial use.

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

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