



## **Drug Utilisation Sub-Committee Outcome Statement 6-7 June 2013**

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 78th meeting on 6-7 June 2013.

DUSC is a national focus of excellence for 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 35 major submissions had been received for the July 2013 meeting of PBAC. DUSC provided detailed advice to the PBAC on projected usage and financial cost for major submissions with high cost, uncertain utilisation, first medicine in class or quality use of medicines concerns. The agenda for the July 2013 PBAC meeting can be found at <http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/agenda/pdf/pbac-meeting-agenda-july-2013-v3.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 have 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](http://www.pbs.gov.au))

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

#### **Dutasteride and dutasteride with tamsulosin for benign prostatic hyperplasia (Utilisation analysis 12 months after PBS listing)**

Utilisation of both dutasteride single agent and dutasteride with tamsulosin during the first year of listing on the PBS was lower than expected. DUSC considered that the following factors may have contributed to lower than expected initial uptake:

- An overestimate of the eligible population or those presenting for treatment
- An overestimate of uptake, perhaps due to patient or urologist preference for surgical over medical management;
- Delayed access to a urologist (which is required for initial prescription).

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

DUSC recommended that the report be prepared for publication on [www.pbs.gov.au](http://www.pbs.gov.au). DUSC requested another utilisation review of dutasteride and dutasteride with tamsulosin when a further 12 months of data are available.

#### **Tobramycin solution for inhalation for management of *Pseudomonas aeruginosa* infection in patients with cystic fibrosis**

##### **(Utilisation analysis 12 months after PBS listing)**

DUSC noted that while the actual number of prescriptions and expenditure for tobramycin solution for inhalation were similar to predicted values, the analysis showed a number of

differences in the predicted versus actual patterns of use in practice, in particular with respect to uptake rate and the number of prescriptions per patient.

DUSC requested another utilisation review of tobramycin solution for inhalation when 24 months of data are available. DUSC requested that the report be forwarded to the Council of Australian Therapeutic Advisory Groups (CATAG) for information because prior to PBS listing tobramycin was usually supplied through hospitals.

DUSC requested that the report be provided to the PBAC for information and prepared for online publication on [www.pbs.gov.au](http://www.pbs.gov.au).

### **Cetuximab and bevacizumab for metastatic colorectal cancer (Utilisation analysis 12 months after PBS listing of cetuximab)**

The review found the utilisation of bevacizumab was similar to predicted at the time of listing. The total number of patients treated with cetuximab was lower than predicted. This may be due to some eligible patients being enrolled in clinical trials or access programs for alternate therapies.

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

### **Disease modifying treatments for multiple sclerosis**

The utilisation analysis included the disease modifying treatments: the interferons, fingolimod and natalizumab. DUSC noted that the number of people supplied with a disease modifying treatment for relapsing-remitting multiple sclerosis appears to have increased with the introduction of the oral agent fingolimod. DUSC considered that revisions to the diagnostic criteria and the availability of oral treatment will potentially increase the number of people with multiple sclerosis treated with a disease modifying treatment.

DUSC commented that the natural history of multiple sclerosis can result in patients having long periods of stability between attacks. It was noted that lifestyle is important in managing multiple sclerosis and that patients may choose to have a treatment break for various reasons, including pregnancy or adverse events. DUSC considered that a better understanding of the patient experience would assist in understanding how disease modifying treatments are used in practice. DUSC recommended a mechanism be developed through which additional consumer input to DUSC analyses can be received and considered in the future. Patient experience is likely to inform use in practice including uptake rates and duration of treatment.

DUSC requested that the report be provided to the PBAC for information and prepared for online publication on [www.pbs.gov.au](http://www.pbs.gov.au).

### **Fingolimod**

#### **(Utilisation analysis 12 month after PBS listing)**

Utilisation of fingolimod was slightly higher than expected in the first year of PBS listing. DUSC considered that the rapid uptake of fingolimod observed in the first few months of PBS listing was likely due to patients moving from a compassionate use program to PBS supply.

DUSC requested that the report be provided to the PBAC for information and prepared for publication on [www.pbs.gov.au](http://www.pbs.gov.au). DUSC requested another utilisation review of fingolimod when a further 12 months of data are available.

## **Antipsychotics**

DUSC had previously raised concern that the utilisation of PBS listed antipsychotics is growing at a higher than expected rate, and requested additional analyses to better understand utilisation.<sup>1</sup> Analysis of PBS prescription data demonstrated that there is high and inappropriate utilisation of antipsychotics in the elderly. The prescription data indicated some use of antipsychotics in very young patients and also suggested possible use of antipsychotics for non-PBS subsidised indications in middle-aged adults. DUSC requested further investigation to verify this use.<sup>2</sup>

DUSC noted that a number of initiatives are underway to support better medication management in residential aged-care, including reducing inappropriate use of antipsychotics and sedative medications.<sup>3</sup>

DUSC highlighted that the level of use of antipsychotics in adults aged 20-59 years appears inappropriate and may indicate use for non-subsidised and off-label indications such as sedation. This is most evident with the high number of prescriptions for the 25mg strength of quetiapine, which is generally not a therapeutic dose to treat the PBS subsidised indications of schizophrenia and bipolar disorder. The use of antipsychotics, rather than sedatives for sedation, raises safety concerns and does not represent quality use of medicines.

DUSC requested that the utilisation report be provided to the PBAC and to NPS MedicineWise, and be prepared for publication in a peer-reviewed journal.

## **Upcoming Utilisation Analysis of PBS Listed Medicines**

The following medicines and therapeutic indications have been selected for consideration at future DUSC meetings.

### **Utilisation analysis 12 months after PBS listing**

- Indacaterol powder for oral inhalation: for chronic obstructive pulmonary disease (COPD).
- Budesonide with eformoterol fumarate dehydrate powder for oral inhalation: extension of listing to include COPD.
- Magnesium tablet: for hypomagnesaemia associated with chronic renal failure in the Aboriginal and Torres Strait Islander population. When recommending listing in July 2011, the PBAC requested that DUSC monitor utilisation.
- Paliperidone palmitate long acting injection: for schizophrenia. The dose relativity accepted by the PBAC for pricing purposes was 1:1.32 for injected risperidone and injected paliperidone, respectively, based on USA sales and Medicare data. In view of the uncertainty regarding the dose relativity, the PBAC considered that this dose relativity should be reviewed in 12 months' time based on PBS data.
- Botulinum toxin type A lyophilised powder for injection: for severe primary axillary hyperhidrosis.
- Denosumab injection: for bone metastasis from breast cancer and hormone resistant prostate cancer.

### **Utilisation analysis of multiple medicines for a therapeutic indication**

- Lenalidomide, bortezomib and thalidomide for multiple myeloma. There have been a number of new listings in this therapeutic area over recent years. The analysis will include an assessment of predicted versus actual use.

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<sup>1</sup> <http://www.pbs.gov.au/industry/listing/elements/dusc-meetings/dos/dusc-dos-oct-2012-v2.0.pdf>.

<sup>2</sup> <http://www.pbs.gov.au/industry/listing/elements/dusc-meetings/dos/dusc-dos-feb-2013.pdf>

<sup>3</sup> [http://www.health.gov.au/internet/ministers/publishing.nsf/Content/1E0F07221D7C5D32CA257B9600023E6F/\\$FILE/MB056.pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/1E0F07221D7C5D32CA257B9600023E6F/$FILE/MB056.pdf).

- Osteoporosis: DUSC reviewed medicines for osteoporosis in October 2012.<sup>4</sup> DUSC requested a subsequent analysis now that more than 12 months has elapsed since the extension of the listing of some agents to include patients with a BMD T-Score between -3.0 and -2.5. At its June 2013 meeting, the DUSC noted that the extent of use of calcium in combination with bisphosphonates should be evaluated as part of this analysis, due to concerns of increased cardiovascular risks with calcium.<sup>5</sup>

## **Other Matters**

### **Fixed dose combination products**

DUSC had previously noted emerging trends with some fixed dose combination (FDC) products such as a higher proportion of patients commencing FDCs without an initial period of use on the individual medicines, and the introduction of FDCs increasing the market size rather than substituting within the existing market.

DUSC requested that a further mapping exercise be undertaken, to identify all PBS listed FDC products, quantify their number, and determine when they were listed for which indications. DUSC recommended that any revision of the Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee in relation to fixed combination products consider inclusion of the following:

- clinical rationale for the products to be available as an FDC;
- evidence that the available products allow for appropriate dose titration;
- explanation of the need for proliferation of dosage forms;
- whether the availability of a subsidised FDC results in clinically inappropriate substitution patterns;
- the potential for increased wastage of a FDC compared with component products when starting treatment on a FDC, titrating the dose of one component, or switching between products.

### **Improving transparency: public release of DUSC utilisation analyses of PBS listed medicines**

DUSC requested that regular and timely communication about its work be provided to the public. The Outcome Statements, published after each DUSC meeting, give a high level summary of the topics discussed at each meeting. The reports of the utilisation analyses will also be published to communicate the activities of DUSC to consumers, industry and researchers interested in the utilisation of PBS medicines.

### **Compassionate Use and Product Familiarisation Programs**

DUSC noted that medicines supplied through compassionate use and product familiarisation programs are not captured in the PBS data, and may distort the likely uptake and estimates of use within the PBS market. DUSC noted pharmacovigilance issues with compassionate use and familiarisation programs, with the potential for gaps in patients' medication histories and lack of electronic prescribing support including detection of drug interactions and warnings.

### **Membership**

DUSC welcomed the appointments of Ms Elizabeth de Somer from Medicines Australia and Ms Belinda Wood from the Generic Medicines Industry Association the industry representatives on DUSC.

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<sup>4</sup> <http://www.pbs.gov.au/industry/listing/elements/dusc-meetings/dos/dusc-dos-oct-2012-v2.0.pdf>

<sup>5</sup> Aust Prescriber 2013;36:5-8.

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

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