



## **Drug Utilisation Sub-Committee Outcome Statement 2 – 3 October 2014**

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 82nd meeting on 2-3 October 2014.

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 2014 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 2014 PBAC meeting can be found at <http://pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda/11-2014>

### **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 ([www.pbs.gov.au](http://www.pbs.gov.au))

DUSC reviewed the utilisation of the following PBS medicines/groups of medicines in October 2014:

#### **Pregabalin for neuropathic pain – 12 months utilisation analysis**

When recommending listing of pregabalin on the PBS, the PBAC accepted the clinical need for an alternative to current treatments for neuropathic pain, but considered that the number of patients eligible for pregabalin was difficult to forecast and that there was potential for use outside the restriction (e.g. for fibromyalgia).<sup>1</sup> The PBAC considered it was essential that the DUSC review usage 12 months after PBS listing.

DUSC found that more patients were supplied pregabalin through the PBS in the first year of listing than anticipated. The number of prescriptions dispensed was similar to expected, but is increasing and utilisation is yet to stabilise. It is unclear at this point in time how pregabalin is being used in clinical practice, including how long people remain on the medicine, doses prescribed, and whether pregabalin is add-on to or used instead of other medicines for neuropathic pain. DUSC considered that interrogation of the data to understand utilisation patterns would be more appropriate with a longer period of data and requested another analysis when 24 months of data are available.

---

<sup>1</sup> <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2012-03/pregabalin>

### **Exenatide for type 2 diabetes**

The number of patients treated with exenatide in the first two years of listing was lower than predicted, however the expected number was reached in the third year. Use of the 5 microgram strength has been higher than expected and DUSC considered several factors may possibly contribute to this pattern including use of exenatide in combination with insulin as an insulin sparing agent, adverse events such as nausea, and an underestimate at the time of listing.

Treatment pathways prior to commencement on exenatide are diverse. Exenatide is mostly used in dual and triple therapy regimens, although there is some use as monotherapy and quadruple therapy. There is use of exenatide outside of the PBS criteria, mostly in combination with insulin and as monotherapy. DUSC requested that the report be provided to the PBAC.

### **Novel Oral Anticoagulants for venous thromboembolism (VTE)**

Use of dabigatran and apixaban for the prevention of VTE in hip and knee replacements is low and stable.

In the first year of listing, the use of rivaroxaban for deep vein thrombosis (DVT) was higher than predicted. This was most likely due to an underestimate of the expected number of patients, duration of treatment and uptake. DUSC requested an analysis of duration of treatment when an adequate period of data becomes available.

It is too early to examine the predicted versus actual use of rivaroxaban for pulmonary embolism because only eight months of data were available at the time of the analysis.

### **Tobramycin solution for inhalation (TSI) for cystic fibrosis**

In the second year of PBS listing, 1,332 patients received TSI for the treatment of *Pseudomonas aeruginosa* infection. The majority of patients under 10 years receive one to three supplies over 12 months. This appears consistent with younger patients receiving one to three months of treatment to eradicate the infection. The patterns of treatment in patients 15 years of age and older were less clear. DUSC considered that this may be due to use of non-PBS treatments or intravenous antibiotics, public hospital supply of larger quantities for convenience, patient stockpiling or prescription-sharing within families, or low adherence to cyclical tobramycin therapy.

### **Mannitol and Dornase Alfa for cystic fibrosis**

The use of dornase alfa has increased steadily since 2004. In the 12 months from May 2013 to April 2014, 1,570 patients received dornase alfa. In the same 12 months, 106 patients received mannitol. The current PBS restrictions for mannitol and dornase alfa do not allow for the combination use of both medicines. DUSC requested that advice be sought from cystic fibrosis clinicians regarding the low uptake of mannitol, and that the report be provided to PBAC.

### **Ezetimibe and simvastatin fixed dose combination for hypercholesterolaemia**

The number of new patients commencing ezetimibe (plain or fixed dose combination presentation) is steady, with approximately 38,000 patients commencing treatment each year. At the end of 2013 over 200,000 patients were on treatment with ezetimibe. DUSC considered that clinical endpoint data outcomes from the IMPROVE-IT study will influence utilisation of ezetimibe in Australia in the future.

The number of patients on the lower strengths of the ezetimibe with simvastatin fixed dose combinations (10-10mg and 10-20mg) is low compared with the higher strength formulations, but has increased over time. There was a further increase in the 12 months after the extended listing for the lower strengths to include patients inadequately controlled on a maximum

tolerated dose of a statin equivalent to 10 or 20mg simvastatin. DUSC considered this to be a higher increase than predicted. DUSC was concerned that there may be instances where the statin is not up-titrated to the maximum tolerated dose before adding ezetimibe. DUSC requested that the report be provided to PBAC for information.

### **Opioid analgesics**

The use of opioid analgesics, measured by prescription counts and Defined Daily Doses (DDD) per 1000 population per day, continues to increase over time. Paracetamol with codeine has the highest rate of use in terms of DDDs/1000population/day. In 2013, oxycodone became the second highest used opioid analgesic, exceeding the use of tramadol. Utilisation of fentanyl, buprenorphine and hydromorphone is also increasing. The utilisation of morphine and tramadol appear to be decreasing.

DUSC noted the DDD for oxycodone and other strong opioids is much higher than doses typically used to treat chronic non-cancer pain; the main type of pain treated with opioids. DUSC considered the true extent of increasing strong opioid use in Australia may be underestimated by looking at DDDs/1000 population/day. DUSC will consider alternate measures of opioid utilisation to better understand use in persistent non-cancer pain.

### **Antibiotics**

The DUSC considered that community antibiotic supply is extensive, high relative to other OECD nations, and increasing in recent years. Almost half of the Australian population were supplied at least one PBS/RPBS antibiotic in 2013.

DUSC considered that there is overuse of antibiotics at the population level. A large proportion of antibiotic prescriptions are for broad and moderate spectrum penicillins and cephalosporins.

The DUSC acknowledged that the PBS data are limited by not including the indication for which the antibiotic is prescribed, and cannot provide direct information on the appropriateness of prescribing or on the contribution to antimicrobial resistance.

DUSC requested that the analysis be published as soon as possible to inform current and future strategies for managing antibiotic resistance and promoting appropriate antibiotic use. DUSC also requested that the report be provided to PBAC for information.

### **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 12 or 24 months after listing**

- Rotigotine for Parkinson's disease when 24 months of utilisation data are available.
- Infliximab and adalimumab for Crohn's disease

#### **Analysis of multiple medicines in a treatment area**

- Hepatitis B medicines
- Pulmonary Arterial Hypertension medicines
- Nutritional products
- Dementia medicines when 24 months of data are available since the May 2013 changes in listings.

## **Other Matters**

### **Membership**

The Chair welcomed Dr Tracey Laba as a member of DUSC.

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).

Professor Geoff McColl  
Chair  
Drug Utilisation Sub-Committee