Drug Utilisation Sub-Committee
Outcome Statement 4 June 2015

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 84th meeting on 4 June 2015.

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 27 major submissions had been received for the July 2015 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 July 2015 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 June 2015:

Dutasteride and dutasteride with tamsulosin for benign prostatic hyperplasia (BPH)
Utilisation of the plain form of dutasteride has remained low and stable, with between 4,600 and 4,900 patients receiving treatment each year from 2012 to 2014. Utilisation of dutasteride with tamsulosin fixed dose combination product has increased steadily, from around31,000 patients in 2012 to over 63,000 in 2014. Overall utilisation has been substantially lower than expected. DUSC considered that the lower than expected utilisation may be due to a number of reasons, including overestimates in eligible patient and uptake numbers, larger than expected proportions of private prescriptions, shorter than expected treatment duration and that treatment must be initiated by a urologist. DUSC considered that the PBS restriction for initiation by a urologist may be limiting patient access to these medicines. The DUSC requested that the report be provided to the PBAC and suggested that the PBAC consider whether there is an ongoing need for treatment with these therapies to be initiated by a urologist.

Icatibant for hereditary angioedema (HAE)
The number of patients dispensed icatibant has been much lower than expected. DUSC considered that this is probably due to an overestimate of the prevalence of HAE from the available literature. The number of injections dispensed per patient has been more than

anticipated, but remains within the upper bound of the range considered by the PBAC. It may be that there is some use of icatibant for less severe attacks but this cannot be ascertained from the PBS prescription data. DUSC noted that the algorithm for treatment is changing and that this may impact on utilisation and cost-effectiveness. DUSC considered that education may assist in optimising use and minimising wastage. The DUSC requested that the report be provided to the PBAC.

Romiplostim and eltrombopag for idiopathic thrombocytopenic purpura (ITP)

The number of patients accessing thrombopoietin receptor agonists (TRA), including romiplostim and eltrombopag, over the first three years of listing on the PBS has been more than predicted. DUSC noted that there was considerable uncertainty about the predicted utilisation estimates at the time of listing, and concern that there was potential for use outside of the PBS restriction in patients who could otherwise undergo splenectomy as data had not been provided to justify the use of romiplostim in preference to splenectomy. DUSC observed that there has been an increasing trend towards patients initiating on TRAs being non-splenectomised which may indicate a change in clinical practice over time. For romiplostim, the proportion of initiating patients who were non-splenectomised increased from 46% in the first year of listing to 76% by the third listing year. DUSC recalled the November 2014 submission for eltrombopag which sought to amend the restriction to allow switching of TRA therapy in patients whose disease is stable. DUSC noted that the mean time on TRA therapy was similar for all initiating patients compared to those who switched their therapy. The DUSC requested that the report be referred to the PBAC.

Aflibercept and ranibizumab for age-related macular degeneration

Between 7,000 and 8,000 new patients start PBS subsidised treatment for wet AMD each year. The majority of patients remain on treatment for many years and therefore the total number of patients being treated continues to grow. Approximately half of patients are treated for at least 4 years. In 2014, 36,739 patients were dispensed a total of 249,772 injections of aflibercept or ranibizumab.

The regimens used in Australian clinical practice have evolved over time and the number of injections per patient in each year of treatment has varied since ranibizumab was PBS listed in 2007. DUSC considered it too early to assess whether the patterns of use of aflibercept will differ from those of ranibizumab in Australian clinical practice. There was rapid uptake of aflibercept following its PBS listing on 1 December 2012, reaching approximately 50% of the AMD market within 6 months. Aflibercept is used in new patients and in patients who have switched from ranibizumab.

The rate of bilateral treatment appears to be increasing, although there is limited information available to estimate this use. DUSC and stakeholders agreed that improved access to data on which eye is being treated would improve interpretation of utilisation data for AMD therapies.

DUSC anticipates that utilisation of aflibercept and ranibizumab will continue to increase into the future given the ageing population and current utilisation patterns. In addition, as utilisation is lower in some states and territories, there is potential for the number of people treated and the number of injections per person to increase if capacity increases.

DUSC referred the report to the PBAC and recommended a subsequent review of utilisation when a further two years of data are available.

Attention deficit hyperactivity disorder (ADHD)
Over the five year period 2010-2014, the number of patients treated with PBS medicines for ADHD has risen steadily, with an annual increase of 5-8%, and 5 year growth of 31%. Similarly the number of prescriptions and PBS expenditure has also increased steadily. Almost all the growth in the number of prescriptions dispensed is accounted for by increasing use of methylphenidate. The majority of prescriptions supplied for methylphenidate are as the modified release forms.

The DUSC considered that the pattern of use in relation to age and gender has not changed substantially over time. A snapshot of medicine use in 2014 shows that 117,403 people were granted authority approval for a PBS medicine for ADHD and 24,232 started an ADHD medicine for the first time. The majority of people commence treatment with an immediate release product, most commonly methylphenidate. Over 875,000 prescriptions were dispensed at a cost to the PBS of approximately $30 million.

DUSC was concerned by some patterns of co-administration of ADHD medicines with other psychotropics; particularly co-supply of an ADHD medicine and an antipsychotic.

The DUSC requested 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

- Ipilimumab and dabrafenib for melanoma;
- Pregabalin for neuropathic pain

Analysis of multiple medicines in a treatment area

- medicines for multiple sclerosis, including a predicted versus actual analysis of the newer medicines, dimethylfumarate and teriflunomide

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