PBAC CONSIDERATION OF THE REPORT OF THE DRUG UTILISATION SUB-COMMITTEE

The PBAC noted utilisation reports with associated stakeholder responses from the June 2017 Drug Utilisation Sub-Committee (DUSC) meeting, which were provided in Items 10.03 to 10.06 of the PBAC Agenda. DUSC minutes relating to these items were provided to the PBAC. The June 2017 DUSC outcome statement is available on the PBS website.

Botulinum toxin type A for chronic migraine
This report compared the predicted versus actual use of botulinum toxin type A (Botox®) for chronic migraine in adults since it was PBS listed for this indication in March 2014. The number of patients treated was substantially higher than predicted. The continuation rate on treatment at 24 weeks was more than double that predicted from trial data and was the main driver of high use. Assessment for continuing PBS-subsidised treatment is based on the number of headache days, which may be subjective.

Outcome
The PBAC recommended that methysergide be removed from the list of prophylactic medicines of which patients are required to trial at least three prior to initiating botulinum toxin type A for chronic migraine. Methysergide is no longer available in Australia and was delisted from the PBS in May 2014. The PBAC recommended no further changes to the current PBS restriction for botulinum toxin type A (Botox®) for chronic migraine. The PBAC noted requests from the Australian and New Zealand Association of Neurologists to add additional options to the list of prophylactic medicines that patients need to trial at least three of prior to botulinum toxin, and to allow retreatment after cycles of 10 weeks. The PBAC considered it has not been presented with sufficient evidence to expand the list of prophylactic medicines or to change the required length of the treatment cycle. Administration more frequently than every 12 weeks has not been assessed for cost-effectiveness and the PBAC did not agree that such a change would not amount to significantly greater overall usage.

Biologic medicines for Crohn disease
This report considered the use of biologic medicines for the treatment of Crohn disease. Use has steadily increased as continuation is much higher than in clinical trials. It is unknown whether the actual pattern of use, with higher continuation rates, is cost-effective.

Outcome
The PBAC noted the higher continuation rates in practice and recalled that higher continuation of biologics in practice has been observed for other conditions; for example, rheumatoid arthritis. The PBAC considered that there is insufficient information to assess the reasons for the higher continuation rates in practice and the impact of this on outcomes and cost-effectiveness. The PBAC considered that the use of biologics for Crohn disease may continue to increase because of the very high continuation rates and if patients receive treatment with biologics earlier in their treatment course. The PBAC recommended that the issue of whether the patterns of

use of biologics in clinical practice are cost-effective be re-evaluated at a later date, taking account of factors that may influence continuation rates and any changes in requirement for surgical procedures and other outcomes. The PBAC considered that the issue should be presented in the context of relevant initiatives and/or changes in costs associated with the entry of biosimilar medicines.

Medicines for ulcerative colitis

This report considered the use of medicines for the treatment of ulcerative colitis; including the predicted versus actual use of biologics for acute severe and moderate to severe disease. Biologics were listed for the treatment of ulcerative colitis relatively recently and their use is low in the context of the entire market, although use is increasing. Mesalazine is the most commonly prescribed medicine for ulcerative colitis; and use of all forms of mesalazine is increasing. The increasing number of prescriptions for mesalazine may be due to more people receiving this treatment or dose escalation. The PBS restrictions for oral mesalazine, balsalazide and olsalazine require the patient to have a documented hypersensitivity reaction to a sulfonamide or be intolerant to sulfasalazine. PBS data indicate that at least half of patients who initiated treatment for ulcerative colitis in 2015 initiated on mesalazine.

Outcome

The PBAC questioned the cost-effectiveness of mesalazine where it is used in place of sulfasalazine or in higher doses. The PBAC deferred further consideration until the DUSC has assessed, to the extent possible from available data, the dose of mesalazine used in practice.

Tobramycin for *P. Aeruginosa* infection in cystic fibrosis

This report considered the use of inhaled tobramycin for the treatment of *P. aeruginosa* infection in patients with cystic fibrosis. This included tobramycin inhalation powder (TIP) and tobramycin solution for inhalation (TSI). The total number of patients using any form of inhaled tobramycin was higher than expected, but the proportion of these that used tobramycin inhalation powder (TIP) was lower than expected.

Outcome

The PBAC noted the report and recommended no further action.