

JULY 2017 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ATAGI review into 23-valent pneumococcal polysaccharide vaccine (23vPPV)</p> <p>0.5 mL injection</p> <p>Pneumovax 23®</p> <p>Australian Technical Advisory Group on Immunisation</p>	<p>Prevention of pneumococcal disease</p>	<p>To request consideration of ATAGI's review into the use of 23vPPV on the National Immunisation Program schedule, as requested by the PBAC in its consideration of 13-valent pneumococcal conjugate vaccine at its July 2016 meeting.</p>	<p>The PBAC noted the review conducted by the Australian Technical Advisory Group on Immunisation (ATAGI) of the clinical place and effectiveness of 23-valent pneumococcal polysaccharide vaccine (23vPPV) on the National Immunisation Program (NIP) schedule and best-practice pneumococcal vaccination recommendations for all adults.</p> <p>The PBAC recalled that when it recommended 13vPCV on a cost minimisation basis to 23vPPV in July 2015, it was cognisant of the potential for the prevalence of the serotypes in 13vPCV to reduce as a result of the 13vPCV infant program that was implemented in 2011. The recommendation was also made given the ATAGI advice that there is unlikely to be a significant benefit of 23vPPV in preventing pneumococcal community acquired pneumonia (CAP) in elderly adults.</p> <p>The PBAC further recalled that it amended the basis of its recommendation to cost-effectiveness against 23vPPV in July 2016, while noting that the cost-effectiveness of 23vPPV had not been considered previously. The July 2016 recommendation was therefore made in conjunction with a request for ATAGI to review the clinical effectiveness of 23vPPV with a view to potentially informing a cost-effectiveness review of 23vPPV compared with no vaccine. The PBAC noted at that time that any outcomes of the review may have implications for 13vPCV.</p> <p>The PBAC noted that only a small number of invasive pneumococcal disease (IPD) cases occur in adults without risk factors, and therefore considered there is likely to be a large opportunity cost associated with vaccinating this population.</p> <p>The PBAC recommended a review of the cost-effectiveness of 23vPPV compared with no vaccination for the currently NIP-funded indications for:</p> <ul style="list-style-type: none"> • non-Indigenous adults aged ≥65 years, with and without risk factors; and • Aboriginal and Torres Strait Islander adults aged ≥50 years, with and without risk factors. <p>The PBAC noted that the results of this review may have implications for the cost-effective price for 13vPCV.</p> <p>Given the high and disproportionate burden of IPD in Aboriginal and Torres</p>

JULY 2017 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
			<p>Strait Islander adults, the PBAC also recommended a review of a stepped economic analysis and financial impact of providing 13vPCV, with or without 1 or 2 doses of 23vPPV, to all Aboriginal and Torres Strait Islander people not previously vaccinated with 7vPCV or 13vPCV.</p> <p>Sponsor comment:</p> <p>Seqirus: The review of the cost-effectiveness of 23vPPV compared with no vaccination will provide an opportunity to demonstrate its ongoing value to protect non-indigenous adults aged ≥65 years and Aboriginal and Torres Strait Islander adults aged ≥50 years against invasive and non-invasive pneumococcal disease in the context of the evolving epidemiology of pneumococcal disease in Australia.</p> <p>Pfizer Australia Pty Ltd: Pfizer Australia are pleased ATAGI have developed best-practice vaccination recommendations for all adults which were considered by the PBAC in July 2017. We are disappointed with the further delay in implementation of the July 2016 positive recommendation for NIP listing of Prevenar 13 for non-Indigenous adults ≥65 years old and Indigenous adults ≥50 years. Pfizer is committed to working with the PBAC and the Office of Health Protection to ensure the timely and equitable access of Prevenar 13 for these adults given the significant burden of pneumococcal pneumonia in older Australians. We seek clarity on the timing of the Prevenar 13 NIP listing implementation for these populations. We look forward to any further reviews of the provision of Prevenar 13 including for all Aboriginal and Torres Strait Islander people not previously vaccinated with Prevenar 7 or Prevenar 13.</p>

JULY 2017 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ATAGI review into pertussis vaccinations</p> <p>dTpa vaccine, 0.5 mL injection</p> <p>Boostrix®, Adacel®</p> <p>Australian Technical Advisory Group on Immunisation</p>	<p>Prevention of pertussis</p>	<p>To request consideration of ATAGI's review of pertussis vaccinations (with a particular focus on the booster doses administered in pre-school and adolescence) on the National Immunisation Program schedule, as requested by the PBAC in its consideration of dTpa vaccination during pregnancy at its July 2016 meeting.</p>	<p>The PBAC noted the review conducted by the Australian Technical Advisory Group on Immunisation (ATAGI) on the clinical place and effectiveness of the pertussis vaccines currently listed on the National Immunisation Program (NIP) schedule. The review was based on commissioned modelling studies of pertussis infection and immunity, which simulated the impact of dose addition and removal, particularly focussing on the clinical place and effectiveness of the pre-school (4 years) DTPa-IPV booster dose (which includes inactivated poliomyelitis) and the adolescent (12-13 years) dTpa booster dose (which includes diphtheria and tetanus).</p> <p>The PBAC considered that on the basis of the results of the modelling, removing either the pre-school or adolescent booster dose would result in a reduction in herd immunity and an increase in the incidence of pertussis infections in infants and across the age spectrum. The PBAC noted that the results indicated a very strong indirect protective effect of both the pre-school and adolescent booster doses for infants. However, the PBAC queried whether adolescents have sufficient interaction with newborns to validate this indirect effect.</p> <p>The PBAC noted that the basis of the assumptions underlying the modelling was not clear and the sensitivity of the model to some of the assumptions was not tested. In particular, the PBAC queried the basis of the 6 year duration of protection assumed in the model for the four booster doses of pertussis (given at 18 months, 4 years and 12-13 years and to pregnant women). The PBAC noted that the impact of this assumption was not explored through sensitivity analysis.</p> <p>The PBAC requested the ATAGI to provide further information on the following matters to inform its consideration:</p> <ul style="list-style-type: none"> • the basis of the assumption of 6 years as the estimate of the mean duration of vaccine protection against transmissible infection for the four booster doses. • sensitivity analyses around the assumed mean duration of vaccine protection for the four booster doses. • the results of an additional modelled scenario in which the 18-month booster dose is removed from the schedule, for comparison with the

JULY 2017 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
			<p>results of removing the pre-school or adolescent doses. The PBAC noted that the main aim of this analysis would be to provide further validation of the model, as opposed to considering removal of this dose.</p> <p>Sponsor comment:</p> <p>Sanofi: Sanofi welcomes the results of the PBAC requested ATAGI modelling of the NIP pertussis schedule. The ATAGI model demonstrates the vital role each vaccination time point plays in the pertussis schedule and justifies the previous recommendations of cost-effectiveness made by the PBAC. The pertussis schedule will continue to provide protection of our most vulnerable infants via the introduction of a maternal dTpa booster on the NIP. Sanofi looks forward to the timely conclusion of the PBAC review.</p> <p>GlaxoSmithKline Australia Pty Ltd: The sponsor had no comment.</p>
<p>AURANOFIN</p> <p>Tablet 3 mg</p> <p>Ridaura®</p> <p>Boucher and Muir Pty Ltd</p> <p>New listing</p>	<p>Unrestricted benefit indicated for rheumatoid arthritis</p>	<p>To request the Unrestricted listing of a new form of auranofin.</p>	<p>The PBAC recommended the temporary listing of a capsule form of auranofin on the PBS on the basis of clinical need. The PBAC considered that there is a clinical need for the supply of this medicine to be maintained on the PBS and that the new form should be listed with the same restrictions, maximum quantity and repeats as the currently listed tablet form.</p>
<p>DOCETAXEL</p> <p>Solution concentrate for I.V. infusion 160 mg in 8 mL</p> <p>Docetaxel Accord®</p> <p>Accord Healthcare Pty. Ltd</p>	<p>Unrestricted</p>	<p>To request an unrestricted listing for a new form of docetaxel.</p>	<p>The PBAC noted the change to the listings processed by the secretariat.</p>

JULY 2017 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>Medical Oncology Group of Australia (MOGA):</p> <p>Barriers to prescribing/accessing oncology drugs</p>	<p>Various</p>		<p>The PBAC considered correspondence from MOGA with the following outcomes:</p> <ul style="list-style-type: none"> • The PBAC considered that for all oncology medicines where an Authority Required listing was recommended due to a risk of use outside the restriction, the risk remains and therefore, the authority level of these listings remain justified. • The PBAC considered that the requirement for a declaration of whether the patient has had, or is planned to have, a transplant could be removed from the written authority application for brentuximab vedotin for the treatment of CD30 positive systemic anaplastic large cell lymphoma, noting that the requirement does not align with the clinical criteria for this indication and is not relevant to determining eligibility for PBS subsidy. • The PBAC recommended amending the restriction wording of pemetrexed for the treatment of mesothelioma to allow treatment in combination with cisplatin or carboplatin.
<p>EZETIMIBE EZETIMIBE with SIMVASTATIN EZETIMIBE with ATORVASTATIN ROSUVASTATIN with EZETIMIBE</p> <p>Various strengths</p> <p>Ezetrol® Vytorin® Atozet® Rosuzet composite pack®</p> <p>Post market review report</p>	<p>High cholesterol</p>	<p>To consider the findings of the final report for the Post market review of ezetimibe.</p>	<p>The PBAC considered the Post- market Review of Ezetimibe Report, stakeholder submissions to the Review, the Sponsor’s Pre PBAC response and ESC and DUSC advice. Overall, the PBAC accepted the key findings presented in the Report. The PBAC noted the evidence on long- term patient outcomes was limited to one study, IMPROVE-IT, and that the eligible patient population in this study was not representative of the current PBS population eligible for subsidised ezetimibe.</p> <p>The PBAC acknowledged the stakeholder comments and recognised the challenges in accurately determining the extent of statin intolerance in the Australian population. However, the PBAC was concerned with the extent of use of ezetimibe outside the PBS restriction and recommended that a price reduction was necessary to restore cost-effectiveness.</p> <p>The PBAC agreed that an Authority Required (Streamlined) listing was most appropriate to maintain ezetimibe’s place as second line therapy, consistent with clinical guidelines and to direct use to the high-risk population that would derive most benefit from ezetimibe therapy.</p>

JULY 2017 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Merck, Sharp and Dohme (Australia) Pty Ltd			<p>The PBAC made a number of other recommendations in its advice to the Minister. These included the removal of the General Statement on Lipid Lowering Drugs and consequent requirement to reformulate the restriction for ezetimibe, the derestriction of statins and the value of Quality Use of Medicine initiatives to ensure optimal first line initiation and up-titration of statin therapy.</p> <p>Sponsor comment: The sponsor had no comment.</p>
<p>GOSERELIN 3.6 mg implant Zoladex Implant®, Astra Zeneca Pty Ltd</p>	<p>For the prevention of premature ovarian failure</p>	<p>To request a change to the restriction to enable treatment to prevent premature ovarian failure under certain conditions.</p>	<p>The PBAC recommended a change to the listing of goserelin 3.6 mg implant as a restricted benefit for the prevention of premature ovarian failure (POF) in pre-menopausal women undergoing treatment with alkylating agents for which there is a risk to fertility. The PBAC recalled that it previously considered that the clinical evidence indicated that goserelin was effective in reducing the risk of POF in women receiving cyclophosphamide treatment. By extrapolation, it was biologically plausible that goserelin would also be effective in other conditions treated with alkylating agents, such as cyclophosphamide, and that it would not be equitable to limit access.</p>