

November 2006 PBAC Outcomes – 1st time decisions not to recommend

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Recommendation
Aspirin, tablet, 650 mg, Ecotrin [®] , Goldshield Healthcare (Australia) Pty Ltd Minor submission	Antipyretic, antiinflammatory, analgesic.	Unrestricted listing	The submission was rejected on the basis of there being no identified clinical need.
		<i>Sponsor's comments</i>	No comment
Ezetimibe, tablet, 10mg, Ezetrol [®] and ezetimibe with simvastatin, tablet, 10 mg-10 mg, 10 mg-40 mg and 10 mg-80 mg, Vytarin [®] , Merck Sharp and Dohme (Australia) Pty Ltd Major submission	Lipid lowering drug	<i>Authority required for initial and continuing treatment of patients, in conjunction with dietary therapy and exercise, who are unable to tolerate 20 mg or greater of a statin or experience a clinically important adverse event and whose cholesterol levels are inadequately controlled with up to 10 mg of a statin.</i>	The PBAC rejected the application to list a new strength of ezetimibe with simvastatin (10 mg – 10 mg) on the grounds of unclear clinical need, unnecessary proliferation of dosage forms and lack of evidence that patients were at a lower risk of side effects with this combination than with a 10 mg dose or higher of a more potent statin. <i>(see also PBAC positive recommendations)</i>
		<i>Sponsor's comments</i>	No comment
Leuprorelin acetate, suspension for subcutaneous injection (modified release), 45 mg injection set, Eligard [®] 6 month, Mayne Pharma Ltd Minor Submission	Prostate cancer	To increase the number of repeats from 0 to 1.	The PBAC rejected the submission on the basis that such a listing that would provide for 12 months treatment would set an undesirable precedent, and that it is possible for the patient to collect the prescription for the next injection at the time the doctor administers the injection provided by the current prescription.
		<i>Sponsor's comments</i>	No comment

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Natalizumab, solution concentrate for I.V. infusion, 300 mg in 15 mL, Tysabri [®] , Biogen Idec Australia Pty Ltd Major submission.	Treatment for multiple sclerosis	Section 100 Authority required <i>for initial and continuing treatment, by neurologist, of clinically definite relapsing-remitting multiple sclerosis in ambulatory patients 18 years or older who meet certain criteria.</i>	The PBAC rejected the submission because although it agreed clinical benefit had been demonstrated the cost-effectiveness ratio was unfavourable and uncertain.
		<i>Sponsor's comments</i>	The sponsor looks forward to working with the PBAC to resolve the issues that have been identified."
Pramipexole, tablet, 0.125 mg and 0.25 mg, Sifrol [®] , Boehringer Ingelheim Pty Ltd Major submission	Treatment for restless legs syndrome	Authority required <i>for use in moderate to severe, idiopathic Restless Legs Syndrome (RLS) who meet certain criteria.</i>	The PBAC rejected the submission on the basis of uncertain clinical benefit and the resulting uncertain cost-effectiveness.
		<i>Sponsor's comments</i>	The sponsor is considering its position regarding any future submission.
Quadrivalent Human Papillomavirus recombinant vaccine, (Types 6, 11,16 ,18), injection, Gardasil [®] , CSL Pharmaceuticals Major submission.	Vaccine	For inclusion on the National Immunisation Program <i>for 12 year old girls and a catch-up program for all girls and women 13-26 years.</i>	The PBAC rejected the submission on the basis of uncertainty about duration of effect and unfavourable cost effectiveness. (See PBAC Outcomes November 2006 Extraordinary Meeting)
		<i>Sponsor's comments</i>	The sponsor disagrees with the decision and refers you to its website for further information: http://www.csl.com.au
Sorafenib, tablet, 200 mg, Nexavar [®] , Bayer Australia Ltd Major submission	Treatment for renal cell carcinoma	Authority required <i>for initial and continuing treatment of advanced (unresectable or metastatic) renal cell carcinoma in patients with WHO performance status of 2 or less.</i>	The PBAC rejected the submission because of uncertain clinical benefit and the resulting uncertain and unfavourable cost effectiveness.
		<i>Sponsor's comments</i>	Bayer has initiated discussion with the PBAC to clarify and address the issues raised.
Strontium ranelate, sachet, 2 g, Protos [®] , Servier Laboratories (Australia) Pty Ltd Major submission	Treatment for osteoporosis	Authority required <i>for initial and continuing treatment for the primary prevention of fractures due to osteoporosis in postmenopausal patients of age 75 or greater with BMD T-score of – 3.0 or less.</i>	The PBAC rejected the submission because of uncertain clinical benefit and uncertain and unfavourable cost effectiveness.

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		<i>Sponsor's comments</i>	The sponsor needs to clarify the decision with the PBAC.