March 2006 PBAC OUTCOMES – "1st time" Decision not to Recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
ANECORTAVE ACETATE, vial, 15 mg per 0.5mL, Retaane® Depot Suspension Alcon Laboratories Pty Ltd Major Submission	Macular degeneration of the retina.	Restricted benefit *for treatment of subfoveal choroidal neovascularisation due to exudative age related macular degeneration, where there is a classic component.*	The PBAC rejected the submission because of inadequate evidence to support the claim that that anecortave acetate is no worse than PDT with verteporfin, in terms of effectiveness and safety.
		Sponsor's comments:	The sponsor will be working with PBAC on other options for a possible listing.
BLOOD B-KETONE ELECTRODE, MediSense® Optium. Abbott Diagnostics Australasia Pty Ltd Major Submission	Test to measure ketones in diabetic patients	Restricted benefit *for quantitatively measuring ketones in diabetic patients who are on insulin therapy for their diabetes, and who are at risk of diabetic ketosis or ketoacidosis, or for use during the management of diabetic ketosis or ketoacidosis, and who thus require an estimation of ketones in the blood.*	The PBAC rejected the submission because of uncertain clinical benefit and uncertain and unacceptable cost-effectiveness.
		Sponsor's comments:	The sponsor disagrees with the decision and will work to address the PBAC's concerns.

BORTEZOMIB, vial, 3.5 mg, Velcade®. Janssen-Cilag Pty Ltd. Major Submission	Multiple myeloma	Authority required for treatment of multiple myeloma patients with a WHO performance status of 0-2 who are unsuitable for thalidomide or are experiencing treatment failure following an adequate trial of thalidomide.	The PBAC rejected the submission because of uncertain clinical benefit over the mix of comparators and an uncertain, but high cost effectiveness ratio.
		Sponsor's comments:	Janssen-Cilag has initiated discussion with the PBAC to clarify and address issues raised.
CARMUSTINE, implant, 7.7 mg, Gliadel® Orphan Australia Pty Ltd Minor submission	Treatment for certain type of brain tumour	Amend authority required restriction	The PBAC rejected the request because of issues with the requested restriction.
		Sponsor's comments:	The sponsor disagrees with the decision.
ERLOTINIB, tablets, 25 mg, 100 mg, 150 mg, Tarceva®. Roche Products Pty Ltd Major Submission	Lung cancer	Authority required *for treatment of patients with locally advanced or metastatic non-small cell lung cancer who have previously received chemotherapy.*	The PBAC rejected the submission because equi-effectiveness with docetaxel had not been demonstrated and uncertain cost-effectiveness in comparison with best supportive care.
		Sponsor's comments:	The sponsor will be considering its position regarding any future course of action.

HYLAN G-F 20, injection, 8 mg per mL, Synvisc®. Genzyme Australasia Pty Ltd Major Submission	Osteoarthritis of the knee	Section 100 Authority required *for the treatment of osteoarthritis of the knee in patients who have not responded to NSAIDs or corticosteroid injections, or are unable to take NSAIDs or have corticosteroid injections for safety reasons.*	The PBAC rejected the submission because of uncertain clinical benefit and uncertain and unacceptable cost-effectiveness.
		Sponsor's comments:	The sponsor needs to clarify the decision with the PBAC and is intending to work towards a positive mutual outcome.
METHYLPHENIDATE HYDROCHLORIDE, tablets extended release, 18 mg, 36 mg, 54 mg, Concerta® Janssen-Cilag Pty Ltd Major Submission	Attention deficit hyperactivity disorder (ADHD)	Authority required for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6-18 years who require continuous coverage over 12 hours.	The PBAC rejected the submission because of uncertain extent of clinical benefit over the comparator and uncertain cost-effectiveness.
		Sponsor's comments:	Janssen-Cilag has initiated discussion with the PBAC to clarify and address the areas of clinical and economic uncertainty.
ROPINIROLE HYDROCHLORIDE, tablets, 0.25 mg, 0.5 mg, 2 mg, Repreve® GlaxoSmithKline Australia Pty Ltd Major Submission	Restless legs syndrome	Authority required listing for the treatment of severe primary restless legs syndrome.	The PBAC rejected the submission because of uncertainty about the extent of clinical benefit and the resulting uncertainty about the cost-effectiveness.
		Sponsor's comments:	The sponsor needs to clarify the decision with the PBAC.

SEVELAMER HYDROCHLORIDE, tablet, 800 mg, Renagel®. Genzyme Australasia Pty Ltd Major Submission	Treatment of complications of renal dialysis	Restricted benefit listing *for treatment of hyperphosphataemia in adult patients with chronic renal disease on dialysis whose serum phosphate is not controlled on other products and where phosphate is greater than 1.8 mmol/L and where CaXP product is greater than 4.5 mmol/L.*	Although the PBAC acknowledged the need for an alternative product to the calcium and metal binders for treating hyperphosphataemia in adult patients with chronic kidney disease on dialysis, the submission was rejected because of a lack of convincing evidence of increased efficacy or safety overall, and a high and uncertain cost-effectiveness.
		Sponsor's comments:	The sponsor needs to clarify the decision with the PBAC and is intending to work towards a positive mutual outcome.
SIBUTRAMINE HYDROCHLORIDE, capsules, 10 mg, 15 mg, Reductil®, Ectiva® Abbott Australasia Pty Ltd. Major Submission	Treatment for obesity	Restricted benefit listing *for the treatment of severe obesity (BMI ≥ 35 kg/m^2)with two or more of the following risk factors:* *- Type 2 diabetes* *- Adequately controlled hypertension (< 145/90)* *- Triglyceride > 150 mg/dL* *- HDL < 50 mg/dL (females) or < 40 mg/dL (males)*	The PBAC rejected the submission because of doubts about the extent of clinical benefit, the resulting uncertain cost-effectiveness and a high potential for use outside the restriction.
		Sponsor's comments:	The sponsor will continue to work with the PBAC to achieve a suitable listing.