JULY 2007 PBAC OUTCOMES - "1st time" Decisions not to Recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
DULOXETINE HYDROCHLORIDE, capsules, 30 mg, 60 mg, Cymbalta® Eli Lilly Australia Pty Ltd Major submission	Depression	Restricted benefit *for major depressive disorders.*	The PBAC rejected the submission because it had failed to demonstrate that duloxetine is non-inferior to the comparator in terms of effectiveness and because of uncertainty about its comparative safety.
		Sponsor's comments	The sponsor will work with the PBAC to clarify the decision and refers you to its website (www.lilly.com.au) for further information.
EXENATIDE, solution for injection, pre-filled pen with 60 doses, 5 microgram per dose, 10 microgram per dose, Byetta® Eli Lilly Australia Pty Ltd Major submission	Type 2 diabetes	Authority required *for Type 2 diabetes in combination with metformin and/or a sulfonylurea, in patients who no longer achieve glycaemic control on metformin and/or a sulfonylurea.*	The PBAC rejected the submission on the grounds of high and uncertain cost effectiveness against the comparators. The weight loss data is difficult to value and has not been shown to translate into morbidity or mortality benefits. PBAC also had some concerns regarding long term safety.
		Sponsor's comments	The sponsor will work with the PBAC to clarify the positioning and the valuation of the claimed benefits. The sponsor notes regulatory agencies have generally accepted the product's safety. The sponsor refers to its own website (ww.lilly.com.au) for more details.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
GALSULFASE (rhASB), solution for IV infusion, 1 mg/mL, 5 mL vial, Naglazyme® Biomarin Pharmaceutical Inc. Major submission	Mucopolysaccharidosis VI (MPS VI)	Authority required *for long term enzyme replacement therapy in patients with Mucopolysaccharidosis VI (MPS VI – N-acetylgalactosamine 4-sulfatase deficiency).*	The PBAC rejected the submission on the basis of unacceptably high cost-effectiveness. However the PBAC indicated that galsulfase meets the criteria for the Life Saving Drugs Program (LSDP), given that it produced a clinical benefit in terms of the 12 minute walk test and that it was plausible that the reduction in urinary GAG levels will be associated with a survival benefit. The PBAC therefore recommended that Government considers including galsulfase on the LSDP.
		Sponsor's comments	The sponsor agrees with the decision and will continue working with the government and looks forward to receiving funding through the Life Savings Drug Program.
HUMAN PAPILLOMAVIRUS, recombinant vaccine (Types 16,18), injection, Cervarix® GlaxoSmithKline Australia Pty Ltd Major submission	Human Papillomavirus	For inclusion on the National Immunisation Program *for 12 and 13 year old girls with a catch-up program for all girls and women aged 13-26 years.*	The PBAC rejected the application on the basis of uncertain cost-effectiveness against the comparator, Gardasil, noting the following: • Cervarix is as effective as Gardasil in protection against the cancer-causing HPV types 16 and 18; • There is uncertainty about the breadth of efficacy of Cervarix in terms of cross protection against other cancer-causing HPV types; and • Gardasil offers protection against genital warts.

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		Sponsor's comments	The sponsor looks forward to working with the PBAC to resolve the issues that have been identified and refers you to its website for further information. http://www.gsk.com.au
IMATINIB MESYLATE, tablets, 100 mg and 400 mg, Glivec® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Imatinib-sensitive rare diseases	Extend the current Section 100 (Special Authority Program) to include *treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). Treatment of adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL); myelodysplastic syndromes/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements; aggressive systemic mastocytosis (SM) without the D816V c-kit mutation or with c-kit mutational status unknown.*	The PBAC rejected the submission on the basis of uncertain clinical benefit and uncertain cost-effectiveness.
		Sponsor's comments	Novartis will work with the PBAC to address the issues identified.

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LAPATINIB, tablet, 250 mg, Tykerb® GlaxoSmithKline Australia Pty Ltd Major submission	Metastatic HER2 positive breast cancer	Section 100 (Special Authority Program) *for use in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress HER2 (ErbB2) and who have received prior therapy including trastuzumab.*	The PBAC rejected the submission on the basis of an unacceptable incremental cost effectiveness ratio.
		Sponsor's comments	The sponsor will be considering its position regarding any future course of action and refers you to its website for further information. http://www.gsk.com.au
METHYLPHENIDATE HYDROCHLORIDE, extended release capsules, 20 mg, 30 mg, 40 mg, Ritalin LA® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Attention Deficit Hyperactivity Disorder (ADHD)	Authority required *for treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents aged 6-18 years who have demonstrated a response to immediate release methylphenidate HCL with no emergence of serious adverse events, and who require coverage beyond that provided by immediate release methylphenidate HCL preparations.*	The PBAC rejected the submission because it did not include sufficient evidence to enable it to conclude that Ritalin LA is non-inferior to Concerta, nor to determine the effectiveness of Ritalin LA compared with immediate release methylphenidate.
		Sponsor's comments	Novartis will work with the PBAC to address the issues identified.

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PARICALCITOL, solution for injection, 5 microgram/mL, 10 microgram/2 mL and capsules 1 microgram, 2 microgram, 4 microgram, Zemplar® Abbott Australasia Pty Ltd Major submission	End stage renal disease	Section 100 (Highly Specialised Drug) *for treatment by a nephrologist of patients with end stage renal disease receiving dialysis who have secondary hyperparathyroidism (iPTH value > 300 pg/mL).*	The PBAC rejected the submission on the grounds of insufficient evidence of superiority over the comparator, calcitriol, to support a cost-effectiveness claim.
		Sponsor's comments	The sponsor aims to address the PBAC's concerns and looks forward to a successful resolution of these matters.
TAZAROTENE, cream, 500 micrograms per g (0.05%) and 1.0 mg per g (0.1%), 30 g, Zorac® Genepharm Australasia Ltd Major submission	Psoriasis	Restricted benefit *for chronic stable plaque type psoriasis vulgaris.*	The PBAC rejected the submission because of uncertain clinical benefit in comparison with calcipotriol.
		Sponsor's comments	Genepharm is working closely with the innovator and manufacturer to resubmit compelling clinical evidence to support the efficacy of Zorac, one of America's leading retinoid creams, against calcipotriol.
SOLIFENACIN SUCCINATE, tablet, 5 mg and 10 mg, Vesicare® Arrow Pharmaceuticals Pty Ltd Major submission	Overactive bladder	Restricted benefit *for the treatment of overactive bladder and symptoms of urge urinary incontinence, urgency or increased frequency in patients where treatment with oxybutynin has failed or is not tolerated.*	The PBAC considered that the data presented in the submission did not match the patient population for whom PBS subsidy was sought, resulting in clinical and economic uncertainties. The submission was therefore rejected on the basis of uncertain clinical benefit and uncertain cost effectiveness.

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		Sponsor's comments	No comment.
TELBIVUDINE, tablet, 600 mg, Sebivo® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Hepatitis B	Section 100 (Highly Specialised Drug) *for use in patients aged 16 or older with chronic hepatitis B who satisfy certain criteria.* *NOTE: PBS-subsidised telbivudine must be used as monotherapy.*	The PBAC rejected the submission because of uncertainty about the cost effectiveness over lamivudine and uncertainty about the efficacy in comparison with entecavir on some secondary outcomes.
		Sponsor's comments	Novartis will work with the PBAC to address the issues identified.