

July 2006 PBAC Outcomes – “1st time” Decisions not to Recommend

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Outcome and Comments
Adefovir dipivoxil, tablet 10 mg Hepsera [®] Gilead Sciences Pty Ltd Major submission	Chronic hepatitis B treatment	Extend Section 100 Highly Specialised Drug listing.	The PBAC rejected the submission because of uncertainty about the clinical claim and in the economic model.
		<i>Sponsor's comment</i>	The sponsor will continue to work with the PBAC to achieve a suitable listing.
Glucosamine hydrochloride, capsule 750 mg Arthro-Aid [®] Arkopharma Australia Pty Ltd Major submission	Osteoarthritis	Restricted benefit listing <i>for symptomatic treatment of osteoarthritis.</i>	The PBAC rejected the submission on the basis of a lack of evidence demonstrating relevant clinical efficacy with an appropriate comparator.
		<i>Sponsor's comment</i>	The sponsor will be considering its position regarding any future course of action.
Ibandronate, tablet, 150 mg (Bonviva Once Monthly [®]) Roche Pharmaceuticals Pty Ltd Major submission	Bone resorptive disorders	Authority required listing <i>for treatment as the sole anti-resorptive agent for established postmenopausal osteoporosis in patients with fracture due to minimal trauma.</i>	The PBAC rejected the submission because of the inadequate evidence of demonstrating no difference between ibandronate and alendronate.
		<i>Sponsor's comment</i>	The sponsor will be considering its position regarding any future course of action.
Nicotinic acid, prolonged (extended) release tablets, 500 mg, 750 mg and 1000 mg (Niaspan [®]) Alphapharm Pty Ltd Major submission	Lipid lowering drug	Restricted benefit listing <i>for use in combination with an HMG CoA reductase inhibitor (statin) in type 2 diabetic patients with dyslipidaemia whose HDL-C levels are inadequately controlled despite monotherapy treatment with a statin.</i>	The PBAC rejected the submission on the basis the comparator was not appropriate and lack of clinical evidence to support the implicit claim that an increase in HDL levels reduces cardiovascular risk.

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		<i>Sponsor's comment</i>	
(Human) Rotavirus vaccine, lyophilised powder and solvent for oral administration, 1 mL dose (Rotarix [®]) GlaxoSmithKline Pty Ltd Major submission	Rotavirus gastroenteritis	Listing on the National Immunisation Program for the vaccination of all infants at 2 and 4 months of age to prevent rotavirus gastroenteritis.	The PBAC rejected the submission because of uncertain cost-effectiveness at the price requested.
		<i>Sponsor's comment</i>	
Rotavirus vaccine, live, oral liquid, pentavalent, 2mL dose, Rota Teq [®] CSL Limited Major submission	Rotavirus gastroenteritis	Listing on the National Immunisation Program for the vaccination of all infants at 2, 4 and 6 months of age to prevent rotavirus gastroenteritis.	The PBAC rejected the submission because of uncertain cost-effectiveness at the price requested.
		<i>Sponsor's comment</i>	The sponsor will be considering its position regarding any future course of action.
Thyrotropin alfa-rch, powder for injection 1.1 mg, Thyrogen [®] Genzyme Australasia Pty Ltd Major submission	For preparation of patients for ablation of thyroid tissue.	<i>Authority required listing for the therapeutic use in post-thyroidectomy patients without known metastatic disease, maintained on hormone suppression therapy in the ablation of thyroid remnant tissue in combination with radioactive iodine in adults 18 years and older.</i>	The PBAC rejected the application on the basis of an uncertain quality of life improvement and uncertain cost-effectiveness.
		<i>Sponsor's comment</i>	

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<p>Tipranavir, soft capsule 250 mg (Aptivus®) Boehringer Ingelheim Pty Ltd Major submission</p>	<p>Treatment of HIV/AIDS</p>	<p>Section 100 Highly Specialised Drug <i>for the treatment, in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily, of HIV infection in antiretroviral experienced adults with:</i> <i>(a) evidence of viral replication (viral load of greater than 10,000 copies per mL) and/or</i> <i>(b) CD4 cell counts of less than 500 per cubic millimetre</i> <i>Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens, including regimens with at least 1 non-nucleoside reverse transcriptase inhibitor, 1 nucleoside reverse transcriptase inhibitor and 2 of the protease inhibitors.</i></p>	<p>The PBAC rejected the submission because of the high and uncertain cost-effectiveness ratio.</p>
		<p><i>Sponsor's comment</i></p>	<p>Boehringer-Ingelheim looks forward to working with the PBAC to address the issues raised by the Committee.</p>
<p>Topiramate, tablets 25 mg and 50 mg, Topamax® Janssen-Cilag Pty Ltd Major submission</p>	<p>Anti-epileptic and migraine prophylaxis</p>	<p>Extend Authority required listing to include migraine prophylaxis in patients who have failed or are contra-indicated to beta-blockers and pizotifen.</p>	<p>The PBAC rejected the submission because of uncertain benefit in the population in whom listing was requested and the resulting uncertain cost-effectiveness.</p>
		<p><i>Sponsor's comment</i></p>	<p>Janssen-Cilag has initiated discussions with the PBAC to clarify and address the issues raised.</p>