

JULY 2011 PBAC MEETING OUTCOMES - "1st time" decisions not to recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>BOCEPREVIR, capsule, 200 mg, Victrelis®</p> <p>Merck, Sharp & Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Hepatitis C</p>	<p>Section 100 (Highly Specialised Drugs Program) Authority required listing for treatment of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who are naïve or who have failed one prior attempt with interferon alfa or peginterferon alfa treatment for hepatitis C and meet certain criteria.</p>	<p>The PBAC rejected the submission on the basis of uncertain cost effectiveness.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor wishes to thank the PBAC for their consideration of this important medicine, and will be working with the PBAC to ensure that the issues raised at the PBAC will be addressed in a re-submission.</p>
<p>CABAZITAXEL, solution concentrate for I.V. infusion, 60 mg in 1.5 mL, Jevtana®</p> <p>Sanofi-Aventis Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Authority required listing for treatment of hormone refractory metastatic carcinoma of the prostate in patients previously treated with a docetaxel containing regimen.</p>	<p>The PBAC rejected the submission on the basis of a high and uncertain cost-effectiveness ratio.</p>
		<p>Sponsor's comments:</p>	<p>Sanofi is disappointed by this decision but is committed to continuing to work with the PBAC to ensure that Jevtana is made available on the PBS for Australian men who have prostate cancer.</p>
<p>DIPHtheria, TETANUS, & ACELLULAR PERTUSSIS (dTpa), injection, 0.5mL, Boostrix®</p> <p>GlaxoSmithKline Australia Pty Ltd</p>	<p>Vaccine</p>	<p>Extend the current National Immunisation Program listing to include active vaccination of both parents of newborn infants, where there is no documented evidence of a dTpa booster having been given in the previous 10 years.</p>	<p>The PBAC rejected the submission on the basis of uncertain clinical effectiveness and high and highly uncertain cost effectiveness.</p>

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Major submission		Sponsor's comments:	GlaxoSmithKline is disappointed by this decision, but will continue to work with PBAC to maximise the role of pertussis vaccination in Australia.
EXENATIDE, powder for injection, 2 mg, Bydureon [®] Eli Lilly Australia Pty Ltd Major submission	Type 2 diabetes	Authority required listing for treatment of type 2 diabetes mellitus in combination with metformin or a sulfonylurea or triple combination therapy with metformin and a sulfonylurea. Sponsor's comments:	The PBAC rejected the submission on the basis of uncertain cost-effectiveness, with particular concern over the model assumptions regarding duration of treatment benefit, timing of the switch to insulin, disutilities associated with GI events and injections, and overestimation of cardiovascular benefits. Eli Lilly appreciates the opportunity to meet with the Chair of the PBAC and work towards a mutually acceptable path forwards for this medicine.
INTERFERON BETA-1a, injection set comprising 1 vial powder for injection 30 micrograms (6,000,000 i.u.) with diluent; injection 30 micrograms (6,000,000 i.u.) in 0.5 mL single dose pre-filled syringe, Avonex [®] Biogen Idec Australia Pty Ltd Minor submission	Multiple sclerosis	Request to change the current Authority required listing for relapsing-remitting multiple sclerosis to Authority required (streamlined).	The PBAC rejected the request for a change to the listing, considering interferon beta-1a for relapsing-remitting multiple sclerosis does not meet the Authority Required (Streamlined) criteria of being a treatment for a chronic and stable long term condition nor that Pharmaceutical Benefits Scheme expenditure would not be jeopardised by changing the listing to Authority Required (Streamlined).

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		Sponsor's comments:	The sponsor has no comment.
IPILIMUMAB, concentrate for I.V infusion, 50 mg in 10 mL, 200 mg in 40 mL, Yervoy [®] Bristol-Myers Squibb Australia Pty Ltd Major submission	Anti-cancer drug	Section 100 (Highly Specialised Drugs Program) Authority required listing for treatment of patients with unresectable stage III or stage IV malignant melanoma who have not responded to or were intolerant to prior systemic therapy for metastatic disease.	The PBAC rejected the submission on the basis of uncertain extent of clinical benefit, uncertain clinical place of therapy, high and uncertain cost-effectiveness ratio and uncertain financial costs.
		Sponsor's comments:	The Sponsor is committed to working with the PBAC to resolve any perceived uncertainties to ensure access is delivered to Australian patients through PBS listing.
RASAGILINE, tablet, 1 mg (as mesylate), Azilect [®] Lundbeck Australia Pty Ltd Major submission	Parkinson disease	Authority required (streamlined) listing for treatment of Parkinson disease as adjunctive therapy in patients being treated with levodopa-decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect.	The PBAC rejected the submission on the basis that the comparator was not appropriate because it did not include the pharmacological analogue, selegiline. Further, the cost-minimisation basis of the submission that flow on from the clinical data were an insufficient basis on which to make a judgement on the cost effectiveness of rasagiline.
		Sponsor's comments:	The sponsor has no comment.
ROFLUMILAST, tablet, 500 microgram, Daxas [®] Nycomed Pty Ltd Major submission	Chronic obstructive pulmonary disease	Restricted benefit listing for maintenance treatment of severe chronic obstructive pulmonary disease in adult patients with chronic bronchitis and a recent history of exacerbations, in combination with long acting bronchodilator treatment.	The PBAC rejected the submission on the basis of uncertain effectiveness and uncertain and likely unacceptable cost effectiveness.

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		Sponsor's comments:	Nycomed Australia acknowledges that the reimbursement for Daxas, a new chemical entity, is difficult as there is inherent uncertainty. Nycomed Australia considers that there is a high unmet clinical need and will continue to work with the PBAC to make Daxas available for this patient population.
<p>SOMATROPIN, injection in 1 mL cartridge (with preservative) 5 mg, 12 mg, Genotropin[®]; powder for injection with diluent in pre-filled pen (with preservative), 5 mg, 12 mg, Genotropin GoQuick[®]; injection with diluent in single use syringe (without preservative) in strengths from 0.6 mg – 2 mg, Genotropin MiniQuick[®]</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	Growth hormone	<p>Extend the current Section 100 (Human Growth Hormone Program) listing to include treatment of adults with severe growth hormone deficiency.</p> <p>Sponsor's comments:</p>	<p>The PBAC rejected the submission on the basis of uncertain clinical benefit and highly uncertain cost effectiveness.</p> <p>Pfizer is disappointed with the PBAC's decision as there is a significant unmet clinical need for patients with severe adult growth hormone deficiency.</p>
<p>SUNITINIB, capsule, 12.5 mg, 25 mg and 50 mg (as malate), Sutent[®]</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	Anti-cancer drug	<p>Extend the current Authority required listing to include treatment of unresectable, well-differentiated pancreatic neuroendocrine tumour in patients who are unsuitable for cytotoxic chemotherapy.</p> <p>Sponsor's comments:</p>	<p>The PBAC rejected the submission on the basis of a high and uncertain incremental cost-effectiveness ratio.</p> <p>Pfizer is disappointed by the decision, but will continue to work with the PBAC to make sunitinib available for this patient population.</p>

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TRASTUZUMAB, powder for I.V. infusion, 60 mg, 150 mg, Herceptin® Roche Products Pty Ltd Major submission	Anti-cancer drug	Extend the current Authority required listing to include treatment of HER2 positive, advanced (equivalent to stage III or IV) adenocarcinoma of the stomach or gastro-oesophageal junction, in patients who meet certain criteria. Sponsor's comments:	The PBAC rejected the submission on the basis of unacceptably high and uncertain incremental cost-effectiveness ratios. In reaching this conclusion, all three scenarios proposed in the submission were considered and rejected. The sponsor has no comment.