

**NOVEMBER 2012 PBAC MEETING OUTCOMES - "1<sup>st</sup> time" Decisions not to Recommend**

<b>DRUG AND FORM</b>	<b>DRUG USE AND TYPE</b>	<b>LISTING REQUESTED BY SPONSOR</b>	<b>PBAC OUTCOME AND COMMENT</b>
<p>APIXABAN, tablets, 2.5 mg and 5 mg, Eliquis®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Major submission (Parallel process)</p>	<p>Anti-thrombotic drug</p>	<p>Extend the current Authority Required listing to include an Authority Required (Streamlined) listing for the prevention of stroke or systemic embolism in a patient with non-valvular atrial fibrillation who meets certain criteria.</p>	<p>The PBAC rejected the submission on the basis that the ICER for apixaban compared to warfarin/aspirin is uncertain and has the potential to be unacceptably high, and also because the PBAC did not accept the claim that apixaban has non-inferior efficacy and superior safety compared to dabigatran and rivaroxaban. The PBAC therefore did not accept the submission's cost-effectiveness claim against dabigatran.</p>
		<p>Sponsor's comments</p>	<p>The Sponsor is committed to working with the PBAC to resolve any perceived uncertainties to ensure access to apixaban in stroke prevention is delivered to Australian patients through PBS listing.</p>
<p>BOCEPREVIR with PEGINTERFERON ALFA-2B and RIBAVIRIN, various packs containing boceprevir 200 mg capsules, ribavirin 200 mg capsules and 4 single use injection pens containing peginterferon alfa-2b powder for injection , Victrelis Pegatron® Combination Therapy</p> <p>Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Hepatitis C</p>	<p>Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for the treatment of chronic hepatitis C in treatment naïve and treatment experienced patients aged 18 years and older who meet certain criteria.</p>	<p>The PBAC rejected the submission on the basis of no demonstrated clinical benefit or unmet clinical need and inadequate comparative clinical evidence to support the cost-minimisation claim.</p>
		<p>Sponsor's comments</p>	<p>The sponsor disagrees with the PBAC decision.</p>

<p>EVEROLIMUS, tablets, 5 mg and 10 mg, Afinitor®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Pancreatic neuroendocrine tumour</p>	<p>Authority Required listing for the initial and continuing treatment of unresectable or metastatic, well or moderately differentiated pancreatic neuroendocrine tumour in a patient who meets certain criteria.</p>	<p>The PBAC rejected the submission on the basis of an inappropriate comparator and the resultant invalid cost minimisation analysis. The PBAC considered that a cost-effectiveness analysis versus placebo (best supportive care including symptomatic treatment with somatostatin analogues) would be a more appropriate approach.</p>
		<p>Sponsor's comments</p>	<p>The sponsor has no comment.</p>
<p>EZETIMIBE, tablet, 10 mg, Ezetrol®; EZETIMIBE with SIMVASTATIN, tablet, 10 mg-10 mg, 10 mg-20 mg, 10 mg-40 mg and 10 mg-80 mg, Vytorin®</p> <p>Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p>Minor submission</p>	<p>High cholesterol</p>	<p>Requests a change to the existing restriction wording from the requirement to have 3 months therapy at the maximum tolerated dose of a statin prior to initiation of ezetimibe or ezetimibe simvastatin, to 6 weeks therapy.</p>	<p>The PBAC rejected the submission on the basis of no demonstrated clinical benefit and the resulting uncertain cost-effectiveness in the context of increased costs to the PBS and Government.</p>
		<p>Sponsor's comments</p>	<p>The sponsor has no comment.</p>
<p>FAMPRIDINE, modified release tablet, 10 mg, Fampyra®</p> <p>Biogen Idec Australia Pty Ltd</p> <p>Major submission</p>	<p>Multiple sclerosis</p>	<p>Authority Required listing for initial and continuing treatment for the symptomatic improvement of walking ability of an ambulatory patient with clinically definite multiple sclerosis who meets certain criteria.</p>	<p>The PBAC rejected the submission on the basis of unclear evidence of clinical benefit and that the economic analysis did not provide sufficient basis to conclude that treatment with fampridine is cost-effective.</p>
		<p>Sponsor's comments</p>	<p>Biogen Idec is willing to work closely with the PBAC to provide appropriate evidence to support clinical effectiveness and cost effectiveness in a future submission, and to construct appropriate restrictions to ensure that responders can</p>

			be adequately identified and funded under the PBS. The Sponsor refers interested individuals to its own website for further information: <a href="http://www.biogenidec.com.au">www.biogenidec.com.au</a>
<p>INGENOL, gel, 0.15 mg per g (0.015%), 70 mcg ingenol mebutate in 0.47 g single use tubes, 3 Picato®</p> <p>LEO Pharma Pty Ltd</p> <p>Major submission</p>	Skin cancer	Authority Required listing for the field treatment of solar keratoses of the face and scalp in patients where topical fluorouracil 5% is clinically inappropriate.	The PBAC rejected the submission on the basis that the clinical claim that treatment of solar keratosis with ingenol reduces the risk of squamous cell carcinoma was not quantified, that the cost effectiveness in the PBS setting is unknown, and that the utilisation is uncertain, and is likely to be high and substantially underestimated in the submission.
		Sponsor's comments	LEO Pharma acknowledges the PBAC recommendation and is committed to working with the Committee to address the stated issues. For further information please refer to <a href="http://www.leo-pharma.com.au">www.leo-pharma.com.au</a>
<p>MILNACIPRAN, capsules, 25 mg, 50 mg and 100 mg (as hydrochloride), Joncia®</p> <p>Pierre Fabre Medicament Australia Pty Ltd</p> <p>Major submission</p>	Fibromyalgia	Restricted Benefit listing for the management of an adult patient with fibromyalgia, after failure of standard treatment options, who meets certain criteria.	The PBAC rejected the submission on the basis of high uncertainty in the clinical claim of non-inferiority with duloxetine and a small benefit and uncertain cost effectiveness compared to placebo.
		Sponsor's comments	Pierre Fabre will continue to work with the Pharmaceutical Evaluation Branch and the PBAC to make milnacipran available for patients with fibromyalgia.
<p>PAZOPANIB, tablets, 200 mg and 400 mg (as hydrochloride), Votrient®</p> <p>GlaxoSmithKline Pty Ltd</p>	Cancer in soft tissue	Extension to the recommended Authority Required listing to include the initial and continuing treatment of advanced (unresectable and/or metastatic) soft	The PBAC rejected the submission on the basis of unacceptably high and uncertain cost-effectiveness.

Major submission		tissue sarcoma in a patient who meets certain criteria	
		Sponsor's comments	GlaxoSmithKline is disappointed with the PBAC decision, but remains committed to working with the PBAC to make pazopanib available on the PBS for advanced soft tissue sarcoma patients.
POSACONAZOLE, oral suspension, 40 mg per mL, Noxafil®  Merck Sharp & Dohme (Australia) Pty Ltd  Minor submission	Antifungal	1) Change the current Authority Required PBS listing to an Authority Required (Streamlined) listing 2) Remove the restriction wording pertaining to the cause of neutropenia.	The PBAC rejected the submission on the basis of inadequate data provided to support requested change.
		Sponsor's comments	The sponsor has no comment.
RANIBIZUMAB, solution for intravitreal injection, 2.3 mg in 0.23 mL, Lucentis®  Novartis Pharmaceuticals Australia Pty Ltd  Major submission	Vision loss	Extend the current Authority Required listing to include the initial and continuing treatment by an ophthalmologist, of visual impairment due to macular oedema secondary to retinal vein occlusion.	The PBAC rejected the submission on the basis of unacceptably high and uncertain cost-effectiveness, which is likely to be substantially higher than estimated in the submission.
		Sponsor's comments	The sponsor has no comment.
TERIFLUNOMIDE, tablet, 14 mg, Aubagio®  Genzyme (Sanofi-Aventis Australia Pty Ltd)  Major submission	Multiple sclerosis	Authority Required listing for the initial and continuing treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory patients who meet certain criteria.	The PBAC rejected the submission on the basis of uncertain clinical benefit, no formal economic analysis provided and uncertain uptake and hence uncertain cost to the PBS.

		Sponsor's comments	Genzyme is disappointed by the recommendation but it is committed to continuing to work with the PBAC to ensure that teriflunomide is available on the PBS for people with relapsing-remitting multiple sclerosis.
<p>VARENICLINE, tablets, 0.5 mg and 1 mg (as tartrate) (titration pack), tablet, 1 mg (as tartrate), Champix®</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	Smoking cessation	Amendment of the NOTE to permit a further course of varenicline treatment in patients who did not cease smoking after a course of varenicline or bupropion treatment, provided 6 months have elapsed between treatments	The PBAC rejected the submission on the basis that inadequate data was presented for the requested change.
		Sponsor's comments	The sponsor has no comment.
<p>VINORELBINE, capsules, 20 mg and 30 mg (as tartrate), Navelbine®</p> <p>Pierre Fabre Medicament Australia Pty Ltd</p> <p>Major submission</p>	Breast cancer	Extend the current Authority Required listing to include an Authority Required (Streamlined) listing for the treatment of advanced breast cancer after failure of standard prior therapy, as a single agent or in combination.	The PBAC rejected the submission on the basis that there was inadequate evidence to support a claim of equivalence in terms of comparative effectiveness and safety between oral and IV vinorelbine and an inappropriate cost-minimisation analysis.
		Sponsor's comments	Pierre Fabre will continue to work with the Pharmaceutical Evaluation Branch and the PBAC to make oral vinorelbine available for patients with advanced breast cancer.