

MARCH 2012 PBAC MEETING OUTCOMES - "1st time" decisions not to recommend

DRUG NAME AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
Dapagliflozin, tablet, 10 mg (as propanediol monohydrate), (Forxiga [®]) Bristol-Myers Squibb Australia Pty Ltd Major submission	Type 2 diabetes	Authority Required (Streamlined) listing for treatment of type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.	The PBAC rejected the submission on the basis of an inadequate comparison across appropriate comparators and uncertain comparative clinical effectiveness.
		Sponsor's comments:	Bristol Myers Squibb will be considering its position regarding any further course of action.
Dapagliflozin, tablet, 10 mg, (as propanediol monohydrate), (Forxiga [®]) Bristol-Myers Squibb Australia Pty Ltd Major submission	Type 2 diabetes	Authority Required (Streamlined) listing for the treatment of type 2 diabetes, in combination with metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of dapagliflozin despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.	The PBAC rejected the submission on the basis of uncertain comparative clinical effectiveness.
		Sponsor's comments:	Bristol Myers Squibb will be considering its position regarding any further course of action.
Ezetimibe with simvastatin, tablet, 10 mg-20 mg, Vytorin [®] Merck Sharp & Dohme (Australia) Pty Ltd Major submission	Lipid lowering drug	Extend the current Authority Required (Streamlined) listing to include treatment, in conjunction with diet and exercise for the primary prevention of major cardiovascular events in patients with moderate to severe chronic kidney disease and who do not fall into a category for which the General Statement for Lipid Lowering Drugs allows PBS subsidised treatment with a statin.	The PBAC rejected the submission on the basis of an inappropriate clinical management algorithm and high and unacceptable cost-effectiveness.
		Sponsor's comments:	The sponsor has no comments.

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Follitropin alfa and Lutropin alfa, powder for injection, 150 I.U.-75 I.U. with diluent, Pergoveris® Merck Serono Australia Pty Ltd Minor submission	Fertility drug	1. Section 100- IVF/GIFT Program listing for patients with severe LH and FSH deficiency who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. 2. Restricted Benefit listing for anovulatory infertility in women with severe LH and FSH deficiency.	The PBAC rejected the submission on the basis of inadequate clinical evidence of comparative effectiveness.
		Sponsor's comments:	The sponsor has no comments.
Imatinib, tablet, 100 mg and 400 mg, (as mesylate) Glivec® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Anti-cancer drug	Change the current Authority required listing for the adjuvant treatment of a patient at high risk of recurrence following complete resection of primary gastrointestinal stromal tumour (GIST), which has been histologically confirmed by the detection of CD117 on immunohistochemical staining, at a dose not exceeding 400 mg per day, from a maximum duration of treatment of 12 months to a maximum duration of treatment of 3 years.	The PBAC rejected the submission on the basis of uncertainty regarding the magnitude of the survival benefit and an unacceptably high cost-effectiveness ratio.
		Sponsor's comments:	The sponsor has no comments.
Linezolid, tablet, 600 mg, Zyvox® Pfizer Australia Pty Ltd Minor submission	Antibiotic	Request to reinstate the rescinded PBAC recommendation for an Authority Required listing for treatment initiated in a hospital for infections due to microbiologically proven, multi-resistant methicillin-resistant Staphylococcus species, where no other antimicrobial agent can be used because of either: demonstrated treatment failure, or laboratory confirmed resistance, or intolerance or potential drug interactions.	The PBAC rejected the request to reinstate the September 2002 PBAC recommendation for listing linezolid 600 mg tablets on the PBS and considered that a major submission would be required to allow a full and contemporary evaluation of the clinical place and cost-effectiveness of linezolid in a tablet formulation only.
		Sponsor's comments:	The sponsor has no comments.

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Rivaroxaban, tablet, 15 mg and 20 mg, Xarelto [®] Bayer Australia Ltd Major submission	Anti-thrombotic drug	Authority Required (Streamlined) listing for two new strengths, 15 mg and 20 mg, for the prevention of stroke and systemic embolism in a patient with non-valvular atrial fibrillation (NVAf), who is at risk of developing stroke or systemic embolism as evidenced by prior stroke (ischaemic or unknown type), TIA or non-CNS systemic embolism or two or more of the following risk factors: i. age ≥ 75 years; ii. hypertension; iii. diabetes mellitus; iv. heart failure and/or left ventricular ejection fraction ≤ 35%	The PBAC rejected the submission because of the uncertainty around the clinical evidence to support the clinical claim and the resultant uncertainty in the economic analysis.
		Sponsor's comments:	Bayer Australia will continue to work with the Pharmaceutical Evaluation Branch and the PBAC to make rivaroxaban available for patients with non-valvular atrial fibrillation.
Taliglucerase alfa, lyophilised powder for injection, 200 units, Elelyso [®] Pfizer Australia Pty Ltd Major submission	Gaucher disease	Section 100 (Highly Specialised Drugs Program) or Life Saving Drugs Program listing for the long-term enzyme replacement therapy for patients with a confirmed diagnosis of Gaucher disease.	The PBAC rejected the submission on the basis of uncertain clinical effectiveness, unknown equi-effective doses and unknown interchangeability with imiglucerase.
		Sponsor's comments:	Pfizer will work with the PBAC and Pharmaceutical Evaluation Branch to address these concerns.