

March 2007 PBAC Outcomes – 1st time decisions not to recommend

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Recommendation
Carmustine implant with polifeprosan 20 7.7 mg (Gliadel [®]) Orphan Australia Pty Ltd Major submission	Anti cancer drug	Extension of restricted benefit listing <i>to include the treatment of recurrent glioblastoma multiforme in patients for whom surgical resection is indicated</i>	The PBAC rejected the submission because of uncertain clinical effectiveness.
		Sponsor's comment	The sponsor will be considering its position regarding any future course of action.
Dasatinib, tablets, 70 mg , 50 mg, 20 mg (Sprycel [®]) Bristol-Myers Squibb Pharmaceutical Australia Pty Ltd Major submission	Anti cancer drug	Listing under the section 100 Special Authority Program for the treatment of acute lymphoblastic leukaemia in adult patients expressing the Philadelphia chromosome or transcript, bcr-abl tyrosine kinase, who are resistant or intolerant to imatinib mesylate.	The PBAC rejected the submission because of uncertain cost-effectiveness.
		Sponsor's comment	The sponsor looks forward to working with the PBAC to resolve the issues that have been identified.
Escitalopram, tablets, 10 mg and 20 mg, and 10 mg/mL oral solution (Lexapro [®]) Lundbeck Australia Pty Ltd Major submission	Anti depressant	Restricted benefit listing for social anxiety disorder (social phobia) and generalised anxiety disorder.	The PBAC rejected the submission because of uncertain cost-effectiveness.
		Sponsor's comment	The sponsor looks forward to working with the PBAC to resolve the issues that have been identified.
Etanercept injection set containing 4 vials pwd for inj 25 mg and 50 mg and 4 pre-filled syringes solvent 1 mL (Enbrel [®]) Wyeth Australia Pty Limited Major submission	Psoriasis, Rheumatoid arthritis Ankylosing spondylitis and psoriatic arthritis	Extension of listing for treatment of chronic severe plaque psoriasis.	The PBAC rejected the submission because of uncertainty about the clinical evidence and a high and uncertain cost effectiveness ratio.
		Sponsor's comment	Wyeth looks forward to working with the PBAC to address the issues raised by the Committee.
Interferon beta-1b injection set of 1 vial pwd for inj 8,000,000 i.u. (250 mcg) and solvent (Betaferon [®]) Schering Pty Limited Major submission	Treatment of multiple sclerosis	Amendment of authority required criteria <i>to allow patients diagnosed using the McDonald Criteria to access treatment rather than the current Poser Criteria.</i>	The PBAC rejected the submission because of uncertain clinical benefit and uncertain cost effectiveness.
		Sponsor's comment	Bayer Schering Pharma will discuss this decision with the PBAC in order to clarify and address the issues raised.

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Recommendation
Lanthanum carbonate, chewable tablets, 500 mg, 750 mg and 1000 mg (Fosrenol [®]) Orphan Australia Pty Ltd Major submission	Management of phosphate levels in renal disease	Authority required listing	The PBAC rejected the submission because of a high and uncertain cost-effectiveness ratio that primarily resulted from a lack of data to conclusively link treatment with patient relevant outcomes.
		Sponsor's comment	The sponsor will be considering its position regarding any future course of action.
Venlafaxine hydrochloride, capsules, 37.5 mg, 75 mg and 150 mg (Efexor-XR [®]) Wyeth Australia Pty Ltd Minor submission	Anti depressant	Listing of a new pack size of 14 capsules per pack with no repeats as per the current pack size.	The PBAC rejected the submission because there is already a mechanism available (ie there is no compulsion to prescribe the maximum quantity) which allows for prescribing of less than the maximum quantity of 28 capsules.
		Sponsor's comment	No comment