

**November 2007 PBAC Outcomes – 1st time decisions not to recommend**

Drug Name and Sponsor	Drug Use and Type	Listing requested by Sponsor	PBAC Recommendation
Idursulfase-rhu, IV infusion, 6mg/3mL, Elaprase <sup>®</sup> Genzyme Australasia Pty Ltd  Major submission	Hunter syndrome (a genetic disorder also known as MPS II))	Section 100 Authority Required for the treatment of Hunter syndrome	The PBAC rejected the application on the basis of unacceptable cost-effectiveness. However the Committee indicated that the use of idursulfase for the treatment of MPS II meets the criteria for the Life Saving Drugs Program (LSDP).
		Sponsor's Comments	The sponsor agrees that Elaprase is an appropriate drug to be listed under the Life Savings Drug Program.
Influenza vaccine, injection, 0.5mL Fluarix <sup>®</sup> , Fluvax <sup>®</sup> , Influvac <sup>®</sup> , Vaxigrip <sup>®</sup> , Influenza Specialist Group  Major submission	Influenza	Inclusion on the National Immunisation Program (NIP) for all persons aged 50-64 years old.	The PBAC rejected the submission because of uncertainty in clinical benefits in terms of hospitalisation and mortality.
		Sponsor's Comments	No comment
Iron sucrose, solution for i.v use, 100 mg/5 mL, Venofer <sup>®</sup> Aspen Pharmacare Australia Pty Ltd  Minor submission	Iron deficiency in patients on chronic haemodialysis	Seeks a less restrictive listing and inclusion as a Section 100 item benefit	The PBAC rejected the submission. The PBAC considered that insufficient data had been provided to recommend first-line listing. Listing under section 100 as a highly specialised drug was rejected because the drug was not considered to be highly specialised.
		Sponsor's Comments	No comment

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Ivabradine, tablet, 5 and 7.5mg Coralan <sup>®</sup> Servier Laboratories (Australia) Pty Ltd  Major submission	Angina (heart pain due to lack of oxygen reaching the heart)	Authority Required – treatment of chronic stable angina due to atherosclerotic coronary artery disease in patients with normal sinus rhythm who are unable to tolerate/contra-indicated to beta blockers.	The PBAC rejected the application because of insufficient evidence to support the claim of superiority over the comparators and uncertain cost-effectiveness.
		Sponsor's Comments	No comment
Rosiglitazone maleate, tablet, 4 and 8 mg, Avandia <sup>®</sup> , Rosiglitazone maleate with metformin hydrochloride, tablet, 2mg/1000mg, 2mg/500mg, 4mg/1000mg, 4mg/500mg, Avandamet <sup>®</sup> , GlaxoSmithKline Australia Pty Limited  Major submission	Type 2 diabetes	Extension of current listing to include use as: monotherapy in type 2 diabetes in patients uncontrolled and contraindicated or intolerant of metformin; and in dual combination therapy with metformin, in uncontrolled type 2 diabetes despite treatment with metformin.	The PBAC rejected the submission because of uncertain clinical benefit, concern about the safety of the drug and the resulting uncertain cost- effectiveness.
		Sponsor's Comments	The sponsor will be considering its position regarding any future course of action.
Trandolapril with verapamil, sustained release tablet, 4 mg – 240 mg, Tarka <sup>®</sup> , Abbott Australasia Pty Ltd  Minor submission	Anti-hypertensive	Requests an amendment to the restriction wording to allow use when a patients is not controlled on either one of the components	The PBAC rejected the submission. The current restriction requiring that a patient is stabilised on treatment with trandolapril 4mg and verapamil hydrochloride 240 mg was considered to be clinically appropriate and consistent with other listings.
		Sponsor's Comments	No Comment

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Zoster virus vaccine, injection, 0.65 mL, Zostavax <sup>®</sup> , CSL Biotherapies – CSL Limited  Major submission	Shingles vaccine	Inclusion on the National Immunisation Program for prevention/reduction of herpes zoster (shingles) and post-herpetic neuralgia (PHN) pain in people 60 years or over.	The PBAC rejected the application on the basis of uncertain cost-effectiveness against the comparator, placebo.
		Sponsor's Comments	No comment