November 2008 PBAC OUTCOMES – "1st time" decisions not to recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
Desmopressin acetate, nasal spray, 10 micrograms per actuation, 6 mL, tablet, 200 micrograms, wafer, 120 micrograms, (Minirin®) Ferring Pharmaceuticals Pty Ltd Minor submission	Synthetic pituitary hormone	To request an increase in the maximum quantity.	Rejected as increased quantities are already available under the current PBS listing and because of concerns regarding promoting inappropriate clinical management of nocturnal enuresis. A NOTE should be added to the spray formulation because of ADRAC reports of hyponatraemia.
		Sponsor's comments:	The sponsor accepts the PBAC recommendation and notes that for primary nocturnal enuresis patients who require an increased maximum quantity, doctors can prescribe these via the authority process, with prior approval from Medicare Australia.
Maraviroc, tablet, 150 mg, 300 mg, (Celsentri®) Pfizer Pty Ltd Major submission	Human Immunodeficiency Virus (HIV) infection	Treatment of antiretroviral experienced adult patients infected with CCR5-tropic HIV-1	Rejected because of uncertain cost effectiveness.
		Sponsor's comments:	The Sponsor notes the PBAC's view that the cost effectiveness is uncertain and will consider its position regarding any future course of action.
Modafinil, tablet, 100 mg, (Modavigil®) Australasian Sleep Association Major submission	Promotes wakefulness	To extend the narcolepsy listing on the PBS	Rejected because of insufficient evidence to support the claim that placebo is the appropriate comparator for modafinil in the first line setting and because of insufficient evidence to substantiate the claim that eligible patients are being denied treatment under the current restriction.

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		Sponsor's comments:	The sponsor needs to clarify the decision with the PBAC.
Oseltamivir, capsules, capsules, 30 mg, 45 mg and 75 mg, powder for oral suspension, 12 mg per mL, (Tamiflu®) Roche Products Pty Ltd Major submission	Anti-viral agent to treat influenza	Treatment of infections due to influenza A and B viruses in adults and children aged one year and older.	Rejected because of uncertain clinical benefit and uncertain cost effectiveness. There is also a high risk of use outside the proposed restriction.
		Sponsor's comments:	The sponsor did not provide any comments.
Paclitaxel, powder for I.V. infusion (suspension), 100 mg, (Abraxane®) Specialised Therapeutics Australia Major submission	Anti-cancer drug	Treatment of advanced breast cancer after failure of prior therapy which includes an arthracycline.	Rejected on the basis of uncertain clinical effectiveness and uncertain cost effectiveness.
		Sponsor's comments:	Specialised Therapeutics Australia is committed to continue working with the PBAC in order to provide equitable access to Abraxane for Australian women with metastatic breast cancer.
Panitumumab, concentrated solution for infusion, 20 mg/mL, (Vectibix®) Amgen Australia Pty Ltd Major submission	Monoclonal antibody	Treatment of KRAS wild-type chemotherapy refractory metastatic colorectal cancer.	Rejected because of uncertain clinical benefit and the resultant high and highly uncertain cost effectiveness.
		Sponsor's comments:	The sponsor looks forward to working with the PBAC to ensure a successful listing.
Poly-L-lactic acid, powder for injection, 150 mg, (Sculptra®) Sanofi-Aventis Australia Pty Ltd	Injectable polymer to restore lost facial volume	For the treatment of facial lipoatrophy caused by antiretroviral therapy in HIV positive patients.	Rejected because of uncertain cost effectiveness. PBAC recognises clinical need.

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Major submission		Sponsor's comments:	Sanofi-Aventis will work with the PBAC to try to find a way forward for the benefit of HIV patients.
Valsartan with hydrochlorothiazide, tablet, 320 mg/12.5 mg, 320 mg/25 mg, (Co-Diovan®) Novartis Pharmaceuticals Minor submission	Hypertension	Requests the listing of two additional strengths	Rejected on basis of insufficient evidence of benefit over previously recommended strengths.
		Sponsor's comments:	The sponsor did not provide any comments.