NOVEMBER 2011 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
Abiraterone, tablet, 250 mg (as acetate), Zytiga® Janssen-Cilag Pty Ltd Major submission	Anti-cancer drug	Authority Required listing for the initial and continuing treatment, in combination with prednisone or prednisolone, of a patient with metastatic advanced prostate cancer (castration resistant prostate cancer) in whom disease progression has occurred following treatment with docetaxel.	The PBAC rejected the submission on the basis of an unacceptably high incremental cost-effectiveness ratio and due to uncertainty regarding the clinical place in therapy.
		Sponsor's comments:	Janssen Cilag continue to work with the PBAC to make abiraterone available under the PBS. Janssen believe that the clinical place of abiraterone (following docetaxel) is clearly defined and will work with the PBAC to address the concerns of inappropriate use beyond the requested indication.
Amino acid formula with vitamins and minerals, 240 mL, ProSure® Abbott Australasia Pty Ltd Minor submission	Medicinal food	Restricted Benefit listing for the treatment of cachexia in patients with advanced pancreatic cancer.	The PBAC rejected the submission on the basis of uncertain cost effectiveness based on their evaluation of data from unrandomised controlled trials
		Sponsor's comments:	Abbott Australasia will be considering its position regarding any future course of action.
Botulinum toxin type a purified neurotoxin complex, lyophilised powder for I.M injection, 100 units, Botox® Allergan Australia Pty Ltd Major submission	Prevention of headaches in chronic migraine	Extend the current Section 100 listing (Botulinum Toxin Program) to include the prophylaxis of headaches in an adult patient with chronic migraine who meets certain criteria.	The PBAC rejected the submission on the basis of uncertain clinical benefit and high and highly uncertain cost effectiveness.
		Sponsor's comments:	Allergan will work with the PBAC to address the remaining issues in order to make this treatment available on the PBS for chronic migraine patients

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Ivabradine, tablets, 5 mg and 7.5 mg (as hydrochloride), Coralan® Servier Laboratories (Australia) Pty Ltd Major submission	Heart failure	Authority Required listing for the initial and continuing treatment of symptomatic systolic heart failure in a patient in sinus rhythm, with heart rate at or above 70 bpm stabilised on conventional therapy, which includes a beta blocker (unless intolerant or contraindicated) at a maximum tolerated dose.	The PBAC rejected the submission because of the high uncertainty around the clinical evidence to support the clinical claim and the resultant high uncertainty in the economic analysis.
		Sponsor's comments:	The sponsor has no comment.
Lacosamide, tablets, 50 mg,100 mg, 150 mg and 200 mg, Vimpat® UCB Australia Pty Ltd Major submission	Epilepsy	Authority Required (Streamlined) listing and extend the current PBS listing to include treatment, in combination with a non-sodium channel target antiepileptic drug, of patients with partial epileptic seizures which are not controlled satisfactorily by first line anti-epileptic drugs.	The PBAC rejected the submission on the basis that the evidence presented did not support the claim of superior clinical efficacy of lacosamide in combination with a non-sodium AED over other second line AEDs in combination with any AED, and on the basis of an inappropriate comparator.
		Sponsor's comments:	The sponsor will continue working with the PBAC to ensure that lacosamide is appropriately accessed by patients that will benefit from this treatment.
Pertussis vaccine-acellular combined with diphtheria and tetanus toxoids (Adsorbed), 0.5 mL, Adacel® Sanofi-Aventis Australia Pty Ltd Major submission	Vaccine	Listing on the National Immunisation Program (NIP) as a single dose booster immunisation against tetanus, diphtheria and pertussis to both parents of newborn infants, where there is no documented evidence of a dTpa booster having been given in the previous 10 years.	The PBAC rejected the submission on the basis of uncertain clinical effectiveness of the cocooning strategy and likely high and highly uncertain cost effectiveness.
		Sponsor's comments:	Sanofi Pasteur is disappointed by the decision and will be considering its position regarding any further action
Prucalopride, tablets (film-coated), 1 mg and 2 mg (as succinate), Resotrans® Janssen-Cilag Pty Ltd	Treatment of constipation.	Restricted benefit listing for the treatment of moderate to severe chronic functional constipation in adults who are intolerant to or are not adequately controlled with both bulk forming agents and osmotic laxatives.	The PBAC rejected the submission on the basis of uncertain clinical effectiveness in the requested PBS population and uncertain cost-effectiveness.

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Major submission		Sponsor's comments:	Janssen will continue to work with the PBAC to provide access to this important treatment on the PBS for Australian patients with moderate-severe functional chronic constipation that is not adequately controlled.
Quetiapine, tablets (modified release), 50 mg, 150 mg, 200 mg, 300 mg and 400 mg (as fumarate), Seroquel XR® AstraZeneca Pty Ltd Major submission	Anti-depressant	Extend the current Authority Required (Streamlined) listing to include the treatment of resistant major depression, as adjunctive therapy.	The PBAC rejected the submission on the basis of inadequate clinical evidence to support a claim of superiority over the nominated comparator and therefore a cost-effectiveness analysis was not acceptable.
		Sponsor's comments:	AstraZeneca will continue to work with PBAC to make Seroquel XR available on the PBS for people with treatment resistant major depression.
Rifaximin, tablet, 550 mg, Xifaxan® Norgine Pty Ltd Major submission	Hepatic encephalopathy	Restricted benefit listing for the prevention of a further recurrence or relapse in a patient who has already had an episode of hepatic encephalopathy.	The PBAC rejected the submission on the basis of high and very uncertain cost effectiveness.
		Sponsor's comments:	The sponsor has no comment.

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Sapropterin, soluble tablet, 100 mg (as dihydrochloride), Kuvan® Merck Serono Australia Pty Ltd Major submission	Treatment of elevated phenylalanine blood levels (rare metabolic disorder)	Section 100 (Highly Specialised Drugs Program) Authority Required listing for the initial and continuing treatment of: 1) hyperphenylalaninaemia (HPA) due to phenylketonuria in patients who are sapropterin responsive and are: a) 10 years of age or younger b) 11 to 17 years of age c) 18 years of age or older who meet certain criteria. 2) hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) or tetrahydrobiopterin (BH4) in pregnant women, who meet certain criteria and are sapropterin responsive 3) HPA due to BH4 deficiency in patients who are sapropterin responsive	The PBAC rejected the submission because of uncertainty around the clinical place in therapy and high and uncertain cost effectiveness.
		Sponsor's comments:	Merck Serono Australia is disappointed with the recommendation and will continue to work with the PBAC to ensure access to this valuable therapy for patients with this rare and serious condition.
Telaprevir, tablet (film-coated), 375 mg, Incivo® Janssen-Cilag Pty Ltd Major submission	Hepatitis C	Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment, in combination with peginterferon-alfa and ribavirin, of chronic hepatitis C in a patient 18 years or older who has compensated liver disease and who has received prior treatment with interferon-alfa or peginterferon-alfa for hepatitis C and meets certain criteria.	The PBAC rejected the submission on the basis of uncertain cost effectiveness, highly uncertain utilisation and uncertainty about the impact of the final product information resulting from the evaluation by the TGA on some aspects of the submission
		Sponsor's comments:	Janssen are working with the PBAC and the PEB to address these concerns

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Vinflunine, solution concentration for I.V. infusion, 50 mg in 2 mL and 250 mg in 10 mL (as ditartrate), Javlor® Pierre Fabre Medicament Australia P/L Major submission	Anti-cancer drug	Authority Required (Streamlined) listing for the treatment of an adult patient with advanced or metastatic transitional cell carcinoma of the urothelial (TCCU) tract after failure of a prior platinum-containing regimen.	The PBAC rejected the submission on the basis of uncertainty about the clinical benefit and a high and highly uncertain incremental cost-effectiveness ratio.
		Sponsor's comments:	On behalf of patients with TCCU, Pierre-Fabre Medicament is disappointed at the recommendation from the PBAC. Pierre-Fabre Medicament Australia is committed to working with the PBAC to explore ways so that vinflunine could be made available via the PBS for patients with TCCU.