November 2008 PBAC OUTCOMES – "Subsequent" decisions not to recommend

DRUG AND FORM	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
Cetuximab, vial, solution for infusion, 2 mg per mL, 50 mL, 5 mg per mL, 20mL, 5 mg per mL, 100 mL, (Erbitux®) Merck Serono Australia Pty Ltd Major submission	Treatment of patients with metastatic colorectal cancer that has been demonstrated to express epidermal growth factor receptor (EGFR) and whose disease has progressed or is refractory to irinotecan based therapy. Cetuximab can be used at the doses recommended either in combination with irinotecan or as a single agent. Cetuximab in combination with radiation therapy is indicated for the treatment of patients with locally advanced squamous cell cancer of the head and neck.	Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the TGA-approved Product Information; Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated.	For use in combination with irinotecan in the treatment of metastatic colorectal cancer (mCRC) in patients with the wild type K-RAS oncogene, following failure of irinotecan and failure of or intolerance to oxaliplatin.	Rejected because of uncertainty about the extent of clinical benefit and the resultant high and uncertain cost-effectiveness ratio.
			Comparator: Usual care (a combination of best supportive care and chemotherapy).	Not accepted. This is a change from the Committee's finding in November 2005 that usual care, a composite of active chemotherapy and best supportive care, was the appropriate comparator and reflects recent advances in knowledge in this area. This also means no costs for chemotherapy can be validly included in the comparator arm of the economic evaluation. There is no evidence that disease which has progressed despite treatment with oxaliplatin, irinotecan and 5-fluorouracil will benefit from further chemotherapy. Best supportive care is therefore appropriate comparator.
			Clinical Claim: Cetuximab plus irinotecan is superior in terms of comparative effectiveness compared to cetuximab monotherapy which is in turn superior compared to Usual Care but associated with more toxicity	Not accepted. The claimed survival benefit based on an analysis of retrospective data extracted from four studies and is highly uncertain.
			Economic Claim: Cost effective.	Not accepted. The ICER is both high and highly uncertain.

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			Sponsor Comments:	Merck Serono Australia is disappointed with this recommendation and will continue to work with the PBAC to ensure access to this targeted therapy for patients with metastatic colorectal cancer.
Oxybutynin transdermal patch, 36 mg, (Oxytrol®) Hospira Pty Ltd Major submission	Oxybutynin transdermal patch is indicated for the treatment of overactive bladder with symptoms of urinary frequency, urgency or incontinence or any combination of these symptoms.	Not listed	Treatment of urge urinary incontinence or urgency due to detrusor instability in a patient who cannot tolerate oral oxybutynin.	Rejected because of uncertain comparative clinical effectiveness and the resulting uncertain cost-effectiveness.
			Comparator: Placebo	Accepted
			Clinical Claim: Transdermal oxybutynin is more effective than placebo, but is associated with more adverse events (application site reactions).	Partially accepted. Trials did not recruit patients representative of the proposed PBS population and overestimate the extent of benefit because of this.
			Economic Claim: Cost-effectiveness	Not accepted. The incremental cost-effectiveness ratio remains uncertain.
			Sponsor Comments:	The sponsor will be considering its position regarding any future course of action.
Tamsulosin, tablet, 0.4 mg, (Flomaxtra®) CSL Limited Major submission	For the relief of lower urinary tract symptoms associated with benign prostatic hyperplasia.	Not listed.	Relief of lower urinary tract symptoms associated with benign prostatic hyperplasia.	Rejected on the basis of unacceptable and uncertain cost-effectiveness.

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DRUG AND FORM	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
			Comparators: Placebo and prazosin	Accepted.
			Clinical Claim: Superior in terms of comparative effectiveness and inferior in terms of comparative safety over placebo, and non-inferior to prazosin.	Partially accepted. The PBAC agreed that the 2 point improvement in the International Prostate Symptom Score over placebo is clinically important, but to a varying extent depending upon which symptom is improved. No formal indirect comparison of tamsulosin and prazosin was presented.
			Economic Claim: Cost effective against placebo, cost-minimisation against prazosin.	Not accepted. The incremental cost-effectiveness ratio over placebo remains unacceptably high and uncertain.
			Sponsor Comments:	The sponsor did not provide any comments.