JULY 2012 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
ERLOTINIB, tablet, 25 mg, 100 mg, 150 mg (as hydrochloride), Tarceva® Roche Products Pty Limited Major submission	Lung cancer	Extend the Authority Required listing to include: Initial and continuing first-line treatment, as monotherapy, of locally advanced (stage IIIB) or metastatic (stage IV) non-small cell lung cancer (NSCLC) in patients with evidence of activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material who do not have progressive disease. *Or alternatively:* Initial and continuing first-line treatment, as monotherapy, of locally advanced (stage IIIB) or metastatic (stage IV) non squamous NSCLC or not otherwise specified NSCLC in patients with evidence of activating mutation(s) of the EGFR gene in tumour material who do not have progressive disease.	The PBAC rejected the application on the grounds of unacceptably high and uncertain cost-effectiveness,
		Sponsor's comments:	The sponsor has no comment.
EZETIMIBE and ATORVASTATIN, pack containing 30 tablets ezetimibe 10 mg, and 30 tablets atorvastatin 10 mg (as calcium), atorvastatin 20 mg (as calcium), atorvastatin 40 mg (as calcium) or atorvastatin 80 mg (as calcium), Ezetrol® Plus Atorva Merck, Sharp & Dohme (Australia) Pty Limited Major submission (Parallel Process)	High cholesterol	Authority Required (Streamlined) listing for the treatment, in conjunction with dietary therapy and exercise, for co-administration with a HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who meet certain criteria.	The PBAC rejected the application because of concerns over the labelling and packaging of the co-pack and because the superiority in terms of efficacy and safety over the fixed dose combination ezetimibe and simvastatin has not been demonstrated
		Sponsor's comments	The sponsor has no comment.

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LINAGLIPTIN, tablet, 5 mg, Trajenta® Boehringer Ingelheim Pty Ltd Major submission	Type 2 diabetes	Extend the current Authority Required (Streamlined) listing to include the treatment of patients with type 2 diabetes in combination with metformin and a sulfonylurea (triple oral therapy).	The PBAC rejected the application on the basis of uncertain comparative clinical effectiveness and considerable economic uncertainty
		Sponsor's comments:	The sponsor has no comment.
METHYLPHENIDATE HYDROCHLORIDE, tablet 18 mg, 27 mg, 36 mg, and 54 mg, (extended release) Concerta® Janssen-Cilag Pty Ltd Major submission	Attention deficit hyperactivity disorder in adults	Extend the current Authority Required listing to include use in patients diagnosed with attention deficit hyperactivity disorder (ADHD) after the age of 18 years.	The PBAC rejected the application on the basis of uncertain efficacy and safety in the proposed PBS population and hence uncertain cost-effectiveness, and high and highly uncertain cost to the PBS.
		Sponsor's comments:	Concerta is already available on the PBS for use in adults who were diagnosed with ADHD ≤ 18 years. This submission requested the same access for all adult patients regardless of the age at which they were diagnosed. We will consult with the PBAC with regards to a future resubmission.
PITAVASTATIN, tablet, 1 mg, 2 mg and 4 mg (as calcium), Livalo® Abbott Australasia Pty Ltd Major submission	Lipid lowering drug	Restricted Benefit listing for use in patients who meet the criteria set out in the General Statement for Lipid Lowering Drugs.	The PBAC rejected the application on the grounds that, although the evidence suggested that pitavastatin may be non-inferior to atorvastatin in terms of LDL-C lowering, superiority in terms of efficacy and safety over simvastatin was not demonstrated.
		Sponsor's comments:	The sponsor has no comment.

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DRUG NAME AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
SAXAGLIPTIN, tablet, 5 mg, (as hydrochloride), Onglyza® Bristol-Myers Squibb Australia Pty Ltd Major submission	Type 2 diabetes	Extend the current Authority Required (Streamlined) listing to include the treatment of patients with type 2 diabetes in combination with insulin.	The PBAC rejected the application on the basis of an inadequate comparison across appropriate comparators, uncertain comparative clinical effectiveness and uncertain cost-effectiveness.
		Sponsor's comments:	Bristol-Myers Squibb is disappointed with the PBAC decision and will explore available options to make saxagliptin available on the PBS for eligible Australian patients who require an alternative to pioglitazone in achieving HbA1c control whilst being treated with insulin.