DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENT
Amino acids - synthetic, formula, powder, 400 g, Neocate Nutra® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for combined intolerance (not infant colic) to cow's milk protein, soy protein and protein hydrosylate formulas.	The PBAC agreed with the advice of the Nutritional Products Working Party and rejected the submission on the basis of uncertain clinical need and uncertain but possibly high utilisation.
		Sponsor's comments:	Nutricia Australia has considered the comments made by the Nutritional Product Working Party and PBAC and look forward to working collaboratively with clinical experts to determine clinical need in Australia.
Bortezomib, powder for injection, 1 mg, Velcade® Janssen-Cilag Pty Ltd Major submission	Treat multiple myeloma in patients ineligible for transplant	Authority required listing in combination with prednisolone and melphalan or cyclophosphamide for the treatment of newly diagnosed multiple myeloma patients who are not eligible for high dose chemotherapy.	The PBAC rejected the submission for cost-effectiveness on the basis that superiority to thalidomide (in combination with melphalan and prednisolone) had not been proven. The PBAC recommended that the cost-minimisation recommendation from the July 2009 meeting should be maintained.
		Sponsor's comments:	Janssen-Cilag has engaged in further constructive discussions with the PBAC and clinicians to address issues raised by the Committee, with a view to ensuring access to bortezomib through the PBS for groups of newly diagnosed patients.

Cetuximab, solution for IV infusion, 2 mg/mL, 50 mL, 5 mg/mL, 20 mL, 5 mg/mL, 100 mL, Erbitux® Merck Serono Australia Pty Ltd Major submission	Cancer treatment	Authority required listing for the first line treatment, in combination with chemotherapy regimens, of patients with previously untreated KRAS wild type metastatic colorectal cancer.	The PBAC rejected the submission on the basis of uncertain clinical benefit and uncertain cost-effectiveness.
		Sponsor's comments:	The sponsor is pleased to be working with the PBAC to ensure access to this important targeted therapy for patients with KRAS Wild Type metastatic colorectal cancer.
Fentanyl citrate, lozenge, 200 micrograms, 400 micrograms, 600 micrograms, 800 micrograms, 1200 micrograms, 1600 micrograms, Actiq® Orphan Australia Pty Ltd Minor submission	Cancer pain	Authority required listing for breakthrough pain in patients with advanced metastatic cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.	The PBAC rejected the submission considering that the requested listing for the treatment of breakthrough pain in patients with advanced metastatic cancer is already covered under the current Palliative Care Schedule listing.
		Sponsor's comments:	The sponsor will be considering its position regarding any future course of action.

Meloxicam, tablet, 7.5 mg, 15 mg, Meloxibell®, Meloxicam-GA® Generic Health Pty Ltd, Genepharm Pty Ltd Minor submission	Anti-inflammatory	Add a 'NOTE' to the listing stating bioequivalence between the tablets and capsules.	The PBAC accepted that generic meloxicam tablets are bioequivalent to the innovator meloxicam tablets and that registration by the TGA had been accepted on that basis. However, the PBAC did not consider that generic meloxicam tablets are bioequivalent and therefore interchangeable with the innovator meloxicam capsules as no direct head to head evidence of bioavailability between the generic meloxicam tablets and the innovator meloxicam capsules was provided in the submissions. Therefore, the PBAC did not recommend that the NOTE regarding bioequivalence between the tablet and capsule dosage forms be added to the restriction.
		Sponsor's comments:	The sponsors have no comment.
Pemetrexed disodium, powder for I.V. infusion, 100 mg (base), 500 mg (base), Alimta® Eli Lilly Australia Pty Ltd Minor submission	Cancer treatment	Re-submission to address cost effectiveness uncertainties in the November 2009 submission for the first-line treatment of non-small cell lung cancer.	The PBAC rejected the submission on the basis of an unacceptably high and uncertain cost-effectiveness ratio.
		Sponsor's comments:	Eli Lilly Australia is disappointed with the decision and will be considering its position regarding any future course of action.

Posaconazole, oral suspension, 40 mg per mL, 105 mL, Noxafil® Schering-Plough Pty Ltd Minor submission	Anti-infective	Transfer to the Section 100 (Highly Specialised Drugs Program) Schedule from the General Schedule.	The PBAC agreed with the advice received from the Highly Specialised Drugs Working Party which concluded that posaconazole does not meet all five highly specialised drugs selection criteria, specifically that posaconazole is not highly specialised and does not have an identifiable patient target group therefore rejected the submission.
		Sponsor's comments:	The sponsor has no comment.
Salbutamol sulfate, oral pressurised inhalation, 100 micrograms (base) per dose (200 doses), CFC-free formulation with spacer, VentSpacer® Medical Developments International Ltd Major submission	Asthma	Restricted benefit for patients who are unable to achieve coordinated use of other metered dose inhalers containing salbutamol or at risk of an acute asthma episode.	The PBAC rejected the submission on the basis of uncertain clinical efficacy and uncertain cost effectiveness.
		Sponsor's comments:	The sponsor has no comment.

Tobramycin sulfate, injection 500 mg (base) in 5 mL (without preservative), Tobra-Day® Phebra Pty Ltd Minor submission	Anti-infective	Request for removal of the word 'systemic' from the restriction.	The PBAC rejected the submission considering that insufficient efficacy and cost effectiveness data was provided to support the proposed change to listing.
		Sponsor's comments:	The sponsor has no comment.