Positive Recommendations made by the PBAC in December 2000

DRUG AND FORM	DRUG USE /TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION & COMMENTS
Alendronate sodium tablet 70 mg (Fosamax®)	To treat osteoporosis	Authority required listing for established osteoporosis in patients with fracture due to minimal trauma	Recommended for listing as requested on a cost-minimisation basis compared with 10 mg strength.
Anastrozole tablet 1 mg (Arimidex®)	A treatment for breast cancer	Restricted benefit listing for treatment of advanced breast cancer in post-menopausal women	Recommended for listing for hormone receptor positive advanced breast cancer in post-menopausal women.
Botulinum toxin type A toxin-haemagglutinin complex 500 Ipsen units per vial (Dysport®)	A treatment for muscle spasm	Section 100 listing for the treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care.	Recommended for listing as requested on the basis of acceptable cost-effectiveness.
Candesartan cilexetil with hydrochlorothiazide 16 mg - 12.5 mg tablet (Atacand Plus®)	For hypertension	Restricted benefit listing for treatment of hypertension in patients who are not adequately controlled with either candesartan or hydrochlorothiazide monotherapy	Recommended for listing for treatment of hypertension in patients who are not adequately controlled with candesartan cilexetil 16 mg on a cost-minimisation basis compared with candesartan 16 mg and hydrochlorothiazide 12.5 mg.
Capecitabine tablets 150 mg and 500 mg (Xeloda®)	Anti-cancer treatment	Authority required listing for advanced or metastatic colorectal cancer.	Recommended for listing as requested on the basis that capecitabine is no worse than 5-fluorouracil and leucovorin in terms of effectiveness and safety.
Carbomer 974 solution 0.3%, 0.5 g x 30 (Poly Gel Lubricating Eye Gel®)	An eye drop for dry eyes	Authority required listing for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye	Recommended for listing as requested, on a cost-minimisation basis compared with carmellose unit dose eye drops.

		drops.	
Donepezil hydrochloride tablets 5 mg and 10 mg (Aricept®)	Alzheimer's disease	Authority required listing for the treatment of mild to moderate Alzheimer's disease diagnosed by a specialist. Continuing treatment only for patients who show improvement.	Recommended for listing on the basis of acceptable cost-effectiveness, with an authority required restriction as follows: Initial treatment of mild to moderately severe Alzheimer's disease. Confirmation of diagnosis must be by a specialist/consultant physician (including a psychiatrist). Continuing treatment, following initial therapy, of mild to moderately severe Alzheimer's Disease in patients with demonstrated improvement in cognitive function as measured by an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE); or a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive subscale (ADAS-cog) for patients with an MMSE baseline score of at least 25; Patients receiving this drug prior to 1 December 2000.
Enoxaparin sodium injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe (Clexane®)	For prevention and treatment of blood clots	Restricted benefit listing for prophylaxis of venous thromboembolism in medical patients bedridden due to acute illness.	Recommended for listing with an authority required restriction for non-surgical patients at high risk of venous thromboembolism who are confined to bed in hospital, on the basis that enoxaparin sodium 40 mg once daily is equivalent to unfractionated heparin 5,000 i.u. twice daily.
Epoetin alfa solution for injection 40,000 iu/mL (Eprex®)	For anaemia	Section 100 listing for treatment of anaemia requiring transfusion associated with chronic renal failure.	Recommended for listing on the basis of the price being acceptable relative to the existing listed strengths of epoetin alfa.
Etoposide phosphate powder for IV infusion 568 mg (equivalent to 500 mg etoposide) and 1.136g (equivalent to 1 g etoposide)	An anti-cancer treatment	Unrestricted listing	Recommended for listing on the basis of the price being acceptable relative to the existing listed strengths of etoposide phosphate.

Etophos® New listing			
Exemestane tablet 25 mg (Aromasin®)	Breast cancer treatment	Restricted benefit listing for treatment of advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate.	Recommended for listing in oestrogen receptor positive advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate, on a cost-minimisation basis with 25 mg exemestane daily being of similar safety and efficacy to 1 mg anastrozole daily and 2.5 mg letrozole daily.
Fluvoxamine maleate tablet 50 mg (Luvox®	For depression and obsessive compulsive disorder	Restricted benefit listing for major depressive disorders and obsessive compulsive disorder.	Recommended for listing with the requested restriction on the basis of the price being acceptable relative to the existing listed strength of fluvoxamine maleate.
Gabapentin capsule 100 mg (Neurontin®)	Epilepsy	Authority required listing for treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.	Recommended for listing with the requested restriction on the basis of the price being acceptable relative to the existing listed strengths of gabapentin.
Ganciclovir capsules 250 mg and 500 mg and ganciclovir sodium powder for infusion equivalent to 500 mg ganciclovir, vial (Cymevene®)	Anti-viral agent	Additional section 100 availability for prevention of cytomegalovirus disease in renal transplant patients.	Recommended for listing under section 100 on the basis that the reduction in CMV disease due to ganciclovir preparations in renal transplantation would be similar to that for heart, liver and bone marrow transplantation and potentially lower costs.
Insulin lispro with insulin lispro protamine injection (human analogue) 100 units (50 units-50 units) per mL, 3 mL cartridge, (Humalog Mix50®)	For diabetics	Unrestricted listing	Recommended for listing as requested on a cost-minimisation basis compared with other insulin lispro products.
Oxycodone hydrochloride capsules 10 mg and 20 mg (OxyNorm®)	Opioid analgesic	Restricted benefit listing for severe disabling pain not responding to non-narcotic analgesics.	Recommended for listing with the requested restriction on the basis of the price being acceptable relative to oxycodone hydrochloride tablet 5 mg.

Pantoprazole tablets 20 mg and 40 mg (Somac®)	A treatment for reflux oesophagitis and peptic ulcer	Transfer to restricted benefit listing for treatment and maintenance of reflux oesophagitis.	Recommended for transfer to restricted benefit listing for gastro-oesophageal reflux disease, initial treatment of peptic ulcer, scleroderma oesophagus and Zollinger-Ellison syndrome, on the basis of acceptable cost-effectiveness in gastro-oesophageal disease at the proposed price.
Protein hydrolysate formula with medium chain triglycerides (Pepti Junior® Alfare® Pregestemil®)	A medical food for inborn errors of metabolism	Allow use in children over 2 years of age with intolerance to cows' milk protein and soy protein.	Recommended for the additional indication, continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in children over 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician, on the advice from the Nutritional Products Working Party of the PBAC.
Rabeprazole sodium tablets 10 mg and 20 mg (Pariet®)	A treatment for reflux oesophagitis and peptic ulcer	Authority required listing for 20 mg strength with 1 repeat for refractory duodenal ulcer or refractory gastric ulcer with proven failure to heal despite eight weeks of continuous therapy with other ulcer healing drugs. Authority required listing for both strengths with 5 repeats for severe refractory oesophagitis proven by endoscopy and for scleroderma oesophagus proven by endoscopy and unresponsive to other measures.	Recommended for listing as requested on a cost-minimisation basis compared with omeprazole/omeprazole magnesium, with 10 mg rabeprazole sodium being equivalent to 10 mg (base) omeprazole magnesium and 20 mg rabeprazole sodium being equivalent to 20 mg (base) omeprazole magnesium.
Ribavirin capsule 200 mg (84, 140, 168 packs) with interferon alfa 2a 18 millioin IU per 1.2 mL (Redipen)	Treatment for hepatitis C	Additional indication for treatment of chronic hepatitis C in patients previously untreated with alfa interferon.	Recommended for listing on the basis of acceptable, but high, cost-effectiveness under section 100 for treatment of hepatitis C in patients previously untreated with interferon alfa with histological

(Rebetron Combination Therapy®)			evidence of Metavir stage 2, 3 or 4 fibrosis or stage 1 with grade A2 or A3 inflammation, ie moderate to severe inflammation, evident on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy), who have abnormal ALT levels in conjunction with documented chronic hepatitis C infection (repeatedly anti-HCV positive and/or HCV-RNA positive.
Rivastigmine capsules 1.5 mg, 3 mg, 4.5 mg and 6 mg (Exelon®)	Alzheimer's disease	Authority required listing for the treatment of mild to moderate Alzheimer's disease diagnosed by a specialist. Continuing treatment only for patients who show improvement.	Recommended for listing on the basis of acceptable cost-effectiveness with an authority required restriction as follows: Initial treatment of mild to moderately severe Alzheimer's disease. Confirmation of diagnosis must be by a specialist/consultant physician (including a psychiatrist). Continuing treatment, following initial therapy, of mild to moderately severe Alzheimer's Disease in patients with demonstrated improvement in cognitive function as measured by an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE); or a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive subscale (ADAS-cog) for patients with an MMSE baseline score of at least 25; Patients receiving this drug prior to 1 December 2000.
Sodium clodronate tetrahydrate capsule (equivalent to 400 mg sodium clodronate) and tablet (equivalent to 800 mg sodium clodronate) (Bonefos®)	For hypercalcaemia (high blood calcium levels)	Restricted benefit listing for multiple myeloma and bone metastases from breast cancer.	Recommended for listing as requested on the basis that sodium clodronate is no worse than disodium pamidronate in terms of effectiveness and safety at the dosages used in the clinical studies (1.6 g orally daily for clodronate and 90 mg by IV infusion disodium pamidronate every 4 weeks).

Tenecteplase powder for injection 40 mg and 50 mg packed in singles with pre-filled syringe water for injections 8 mL and 10 mL (Metalyse®)	For use in heart attack to break down the clot	Restricted benefit listing for treatment of myocardial infarction within 12 hours of onset of attack.	Recommended for listing as requested on a cost-minimisation basis compared with alteplase and reteplase, with 44.6 mg tenecteplase (40 mg and 50 mg) being equivalent to 100 mg alteplase and 20 units reteplase.