JULY 2007 PBAC OUTCOMES – POSITIVE RECOMMENDATIONS

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE, powder and tablet, 60x17 g stick packs with 4x15 tablets, Add Ins® Scientific Hospital Supplies Minor submission	Food	Restricted benefit for phenylketonuria.	The PBAC recommended listing as requested on a gram for gram of protein pricing basis.
AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE AND TYROSINE, oral liquid 130 mL TYR Express Cooler® Vitaflo Australia Pty Ltd Minor submission	Food	Restricted Benefit for tyrosinaemia.	The PBAC recommended listing on a gram for gram of protein pricing basis with TYR Express powder.
AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE, oral liquid 250 mL, PKU Start ® Vitaflo Australia Pty Ltd Minor submission	Food	Restricted benefit for phenylketonuria.	The PBAC recommended listing as requested on a gram for gram of protein pricing basis.
AMINO ACIDS-SYNTHETIC FORMULA, compound powder 400 g, Elecare®	Food	Authority required for eosinophilic oesophagitis (EO) in a patient 18 years of age or less.	The PBAC recommended listing for the treatment of a patient aged 18 years of age or less on the basis of acceptable cost-effectiveness compared to standard medical management. Continuing

Abbott Australasia Pty Ltd Minor submission			treatment is to be limited to those patients who demonstrate a response to an initial three month course of treatment.
ATAZANAVIR SULFATE, capsule, 300 mg (base), Reyataz® Bristol-Myers Squibb Pharmaceuticals Minor submission	Human immunodeficiency virus (HIV)	Section 100 (Highly Specialised Drug) for a new strength of a currently listed drug for the same indication.	The PBAC recommended listing as requested.
BORTEZOMIB, powder for injection 3.5 mg, Velcade® Janssen-Cilag Pty Ltd Minor submission	Multiple myeloma	Authority required for initial and continuing treatment of multiple myeloma in patients who have failed specified other therapy, have undergone or are ineligible for a primary stem cell transplant and who meet certain criteria.	The PBAC recommended listing for the treatment of multiple myeloma for patients who meet certain criteria on the basis of acceptable cost-effectiveness when compared to a mixture of salvage treatments. Eligibility for continuing treatment would be determined by response at the end of cycles 4 and 8.
CHOLESTYRAMINE, sachets 9.4 g (equivalent to 8 g cholestyramine), 50, Questran Lite® Bristol-Myers Squibb Pharmaceuticals Minor submission	Bile acid sequestrant and lipid lowering agent	To seek re-listing on a short-term basis while stock remains available.	The PBAC recommended re-listing as requested.
CLINDAMYCIN, capsule 150 mg, Cleocin® Kenral Division of Pharmacia Australia Pty Limited, and Dalacin® Pharmacia Australia Pty Limited Minor submission	Antibiotic	A change to the maximum quantity from 25 to 24 to reflect a change of pack size.	The PBAC recommended listing as requested.
DARUNAVIR ETHANOLATE, tablet, 300 mg (base), Prezista® Janssen-Cilag Pty Ltd	Human immunodeficiency virus (HIV)	Section 100 (Highly Specialised Drug) for treatment, in combination with 100 mg ritonavir and with other antiretroviral agents, of human	The PBAC recommended listing for the treatment of HIV infection in antiretroviral experienced patients in combination with other antiretroviral agents on the basis of

Major submission		immunodeficiency virus (HIV) infection in antiretroviral experienced patients.	high and acceptable incremental cost-effectiveness compared with tipranavir.
DASATINIB, tablet, 20 mg, 50 mg, 70 mg, Sprycel® Bristol-Myers Squibb Pharmaceuticals Minor submission	Acute lymphoblastic leukaemia	Authority required for adults with acute lymphoblastic leukaemia, expressing the Philadelphia chromosome or the transcript BCR-ABL kinase, who are resistant to or intolerant of, prior therapy.	The PBAC recommended listing for the treatment of patients with acute lymphoblastic leukaemia, expressing the Philadelphia chromosome or the transcript bcr-abl kinase, who are resistant to, or whose disease has relapsed on, prior therapy. The PBAC considered that listing dasatinib in this small patient group was consistent with the intention of its 'Rule of Rescue' guidelines.
DIPHTHERIA AND TETANUS VACCINE, adsorbed, diluted for adult use, injection 0.5 mL in pre-filled syringe, ADT Booster® CSL Limited Minor submission	Vaccine	Amendment to the Note for consistency with the Australian Immunisation Handbook.	The PBAC recommended the Note be amended to read: NOTE: For immunisation of adults and children aged greater than or equal to eight years.
DOCETAXEL, injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL and injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single use vial solvent 6 mL, Taxotere® sanofi-aventis Australia Pty Ltd Major submission	Prostate cancer	Amend authority required listing to include treatment of hormone refractory prostate cancer.	The PBAC recommended, at an extraordinary PBAC meeting, listing as an authority required benefit for the treatment of androgen independent (hormone refractory) carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60% on the basis of an acceptable incremental cost-effectiveness ratio per quality adjusted life year at the price proposed. Docetaxel must be used as first line chemotherapy and administered in three weekly cycles.
EFALIZUMAB, powder for injection	Plaque psoriasis	Proposed change for consistency	The PBAC had no objection to the

125 mg, Raptiva® Serono Australia Pty Ltd Minor submission		with infliximab listing.	Secretariat's proposal to change the restriction for severe chronic plaque psoriasis to allow efalizumab to be used either as a single agent or in combination with methotrexate for consistency with the infliximab listing.
ETANERCEPT, 50 mg single use pre-filled syringe x 4, Enbrel® Wyeth Pharmaceuticals Pty Ltd Minor submission	Plaque psoriasis, rheumatoid arthritis, polyarticular course juvenile chronic arthritis	Additional dosage form for use in patients 18 years and older.	The PBAC had no objection to listing this strength under Section 100 for use in patients 18 years or older with polyarticular course juvenile chronic arthritis.
ETANERCEPT, all strengths, Enbrel® Wyeth Pharmaceuticals Pty Ltd Minor submission	Plaque psoriasis, rheumatoid arthritis, polyarticular course juvenile chronic arthritis.	Proposed change for consistency with infliximab listing.	The PBAC had no objection to the Secretariat's proposal to change the restriction for severe chronic plaque psoriasis to allow etanercept to be used either as a single agent or in combination with methotrexate for consistency with the infliximab listing.
FLUCONAZOLE, solution for I.V. infusion 400 mg in 200 mL, Baxter Fluconazole® Baxter Healthcare Pty Limited Minor submission	Antifungal	Listing of an additional strength of a currently listed drug.	The PBAC had no objection to listing a new strength for the same circumstances as the currently listed products.
GLUCOSE INDICATOR-BLOOD, electrode strips, 50, Optimum Omega® Abbott Diabetes Care Minor submission	Testing strips for use by diabetics	Unrestricted benefit.	The PBAC had no objection to listing an additional brand of blood glucose test strips.
IMATINIB MESYLATE, tablet, 100 mg (base), 400 mg (base), Glivec®	Acute lymphoblastic leukaemia (ALL)	Extend the current Section 100 (Special Authority Program) to include treatment in combination with chemotherapy for newly diagnosed	The PBAC recommended listing for the treatment of acute lymphoblastic leukaemia (ALL) expressing the Philadelphia chromosome or transcript,

Novartis Pharmaceuticals Australia Pty Ltd Major submission		patients with acute lymphoblastic leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase. Extend the current Section 100 (Special Authority Program) to include treatment as monotherapy in relapsed or refractory adult patients, with acute lymphoblastic leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase.	bcr-abl tyrosine kinase (Ph +ve) in newly diagnosed patients in combination with chemotherapy on the basis of an acceptable cost-effectiveness ratio compared to chemotherapy alone. The PBAC rejected the application for use as monotherapy in relapsed or refractory patients on the basis of an unacceptably high and uncertain cost-effectiveness ratio.
INFLIXIMAB powder for IV infusion, 100 mg, Remicade® Schering-Plough Pty Ltd Major submission	Crohn's disease (children)	Extend current Section 100 (Highly Specialised Drug) listing to include the treatment of moderate to severe Crohn's disease in paediatric patients who have an inadequate response to conventional therapies.	The PBAC recommended listing for the treatment of Crohn's disease in patients aged 6-17 years inclusive who are refractory to conventional therapies, on the basis of acceptable cost-effectiveness compared to placebo. A continuation rule was required not only to ensure that use remained cost-effective, but also to reduce the potential for harm due to the risk of infection and malignancy, following long-term usage.
IRBESARTAN with HYDROCHLOROTHIAZIDE, tablet, 300 mg-25 mg, Avapro HCT® and Karvezide® Bristol-Myers Squibb Australia and sanofi-aventis Australia Pty Ltd Minor submission	Hypertension	Listing of an additional strength of a currently listed combination product.	The PBAC recommended listing the new strength under the same circumstances as the currently listed products.
IRINOTECAN HYDROCHLORIDE, concentrated injection vial, 500 mg in 25 mL, DBL®Irinotecan Injection	Metastatic colorectal cancer	Listing of an additional strength of a currently listed drug.	The PBAC recommended listing the new strength under the same circumstances as the currently listed products.

Mayne Pharma Ltd Minor submission			
LUMIRACOXIB, tablet, 100 mg, Prexige® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Osteoarthritis	Listing of lower strength of a currently listed drug.	The PBAC recommended listing the new strength under the same circumstances as the currently listed product.
METHYLPHENIDATE HYDROCHLORIDE, tablet (extended release), 18 mg, 36 mg and 54 mg, Concerta®, Janssen-Cilag Pty Ltd Minor submission	Attention deficit hyperactivity disorder (ADHD)	Request from Medicare Australia to amend wording of restriction to replace 'child or adolescent' with 'patient'.	The PBAC recommended amendment of the current restriction to replace "a child or adolescent aged between 6 to 18 years inclusive" with "a patient aged between 6 to 18 years inclusive". The company had expressed no objection to this change.
METHYLPHENIDATE HYDROCHLORIDE, tablet (extended release), 27 mg, Concerta® Janssen-Cilag Pty Ltd Minor submission	Attention Deficit Hyperactivity Disorder (ADHD)	Listing of an additional strength of a currently listed drug.	The PBAC recommended listing the new strength under the same circumstances as the currently listed products. The PBAC also recommended a minor amendment to the wording of the restriction replacing the "a child or adolescent aged between 6 to 18 years inclusive" with "a patient aged between 6 to 18 years inclusive".
MILK POWDER-LACTOSE FREE FORMULA, infant formula powder 900 g, S-26 LF®, Wyeth Pharmaceuticals and lactose-pre-digested powder infant formula 900 g, Karicare De-Lact®, Nutricia Australia Pty Limited MILK POWDER-LACTOSE MODIFIED, lactose-predigested powder 900 g, Digestelact®,	Food	Request from Medicare Australia to add the hydrogen breath test as a mean to demonstrate lactose intolerance.	The PBAC recommended amending the current authority required listings to include the hydrogen breath test as an alternative method to prove chronic lactose intolerance.

Sharpe Laboratories Pty Ltd Minor submission			
MINOXIDIL, tablet, 10 mg, Loniten®, Pharmacia Australia Pty Ltd Minor submission	Hypertension	Change the restriction to enable cardiologists and nephrologists to prescribe the drug in private rooms.	The PBAC recommended the authority required restriction be amended to read: "Severe refractory hypertension. Treatment must be initiated by a consultant physician."
OXALIPLATIN, solution concentrate for IV infusion, 200 mg in 40 mL, Eloxatin® sanofi-aventis Australia Pty Ltd Minor submission	Colorectal treatment	Listing of an additional strength of a currently listed drug.	The PBAC recommended listing the new strength under the same circumstances as the currently listed products.
PEGFILGRASTIM, injection, single use pre-filled syringe, 6 mg in 0.6 mL, Neulasta® Amgen Australia Pty Ltd Major submission	Prevention of neutropenia	Extend the current Section 100 (Highly Specialised Drug) listing to include primary prophylaxis of chemotherapy induced neutropenia in patients with low-grade Non-Hodgkin's Lymphoma receiving an anthracycline containing regimen.	The PBAC recommended extension of the Section 100 (Highly Specialised Drug) listing to include the treatment of patients with low grade non-Hodgkin's lymphoma receiving an anthracycline on a cost-effectiveness basis over the comparator, no prophylaxis.
PERINDOPRIL ARGININE with INDAPAMIDE HEMIHYDRATE 2.5 mg-0.625 mg, tablet, Coversyl Plus LD 2.5 mg/0.625 mg® Servier Laboratories (Australia) Pty Ltd Minor submission	Hypertension	Unrestricted listing of a lower strength of a currently listed combination product.	The PBAC recommended listing as requested.
PERINDOPRIL ARGININE with INDAPAMIDE HEMIHYDRATE, tablet 5 mg-1.25 mg, Coversyl Plus®	Hypertension	Amend the restriction to allow for patients to be up-titrated and reach blood pressure targets.	The PBAC had no objection to amending the wording of the restriction to allow for patients to be up-titrated with the combination product.

Servier Laboratories Australia Pty Ltd Minor submission			
QUETIAPINE FUMARATE, tablet, 25 mg (base), 100 mg (base), 200 mg (base), 300 mg (base), Seroquel® AstraZeneca Pty Ltd Major submission	Bipolar 1 Disorder	Authority required as monotherapy for the treatment of Bipolar 1 Disorder.	The PBAC recommended listing for treatment, as monotherapy, of an acute episode of mania associated with bipolar 1 disorder on a cost-minimisation basis compared with olanzapine.
RILUZOLE, tablet, 50 mg, Rilutek® sanofi-aventis Australia Pty Ltd Minor submission	Amyotrophic lateral sclerosis (ALS)	To change the wording of the initial treatment authority to allow disease duration of 5 years or less.	The PBAC recommended the requirement that the duration of amyotrophic lateral sclerosis be amended to 5 years or less prior to commencement of riluzole.
SEVELAMER HYDROCHLORIDE, tablet, 800 mg, Renagel® Genzyme Australasia Pty Ltd Major submission	Hyperphosphataemia	Authority required for treatment of hyperphosphataemia in an adult with chronic kidney disease on dialysis.	The PBAC recommended listing for the treatment of hyperphosphataemia in adults with chronic kidney disease on dialysis, on the basis of acceptable cost-effectiveness compared to calcium in the context of a high clinical need.
SITAXENTAN, tablet, 100 mg, Thelin® Encysive Pharmaceuticals Inc. Major submission	Pulmonary arterial hypertension	Section 100 (Highly Specialised Drug) listing for treatment of pulmonary arterial hypertension in patients with NYHA/WHO Functional Class III symptoms to improve exercise ability.	The PBAC recommended listing for the treatment of primary pulmonary arterial hypertension in patients with NYHA/WHO Functional Class III symptoms, and primary pulmonary hypertension associated with connective tissue disease on a cost-minimisation basis compared to bosentan.
STRONTIUM RANELATE, sachet, 2 g, Protos® Servier Laboratories (Australia) Pty Ltd Major submission	Osteoporosis	Authority Required listing for the treatment of established postmenopausal osteoporosis ie prevalent fracture.	The PBAC recommended listing as the sole PBS-subsidised antiresorptive agent for osteoporosis in a woman aged 70 years or older with a bone mineral density (BMD) T-score of -3.0 or less on a cost minimisation basis compared to alendronic acid.

TRASTUZUMAB, powder for I.V. infusion, 150 mg, (Herceptin®) Roche Products Pty Ltd Minor submission	Breast cancer	Request from the PBAC Secretariat to remove the two "grandfather initial" restrictions from the PBS listing for the treatment of early breast cancer.	The PBAC had no objection to the Secretariat's proposal to remove the two "grandfather initial" restrictions from the PBS listing for the treatment of early breast cancer. The PBAC noted that the sponsor also had no objection to the removal of the grandfather restrictions.
TRIGLYCERIDES - MEDIUM CHAIN, FORMULA, powder, 400 g, MCT Step 1® Vitaflo Australia Pty Ltd Minor submission	Food	Restricted benefit for chylous ascites; chylothorax, fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders; hyperlipoproteinaemia type 1; long chain fatty acid oxidation disorders.	The PBAC recommended listing on a cost minimisation basis compared with Monogen at an equivalent cost per kilojoule of formula.
TSP (TAMARINDUS INDICA SEED POLYSACCHARIDE) eye drops, daily dose units, 1%, 0.5 mL, 20, Visine Professional Intensive Dry Eye Daily®, Johnson and Johnson Pacific Pty Ltd Minor submission	Dry eyes	Authority required listing for the treatment of severe dry eye syndrome in a patient who is sensitive to preservatives in multi dose eye drops.	The PBAC recommended an authority required listing on a cost-minimisation basis compared with carmellose.
VARENICLINE TARTRATE, tablet, 0.5 mg, 11 and 1 mg, 14 and 1 mg, 28 and tablet 1 mg, 56, Champix® Pfizer Australia Pty Ltd Major submission	Aid smoking cessation	Authority required for short term treatment to aid smoking cessation in adults aged 18 years and older.	The PBAC recommended listing as a short-term treatment to aid smoking cessation in patients aged 18 years of age or older on the basis of an acceptable cost-effectiveness compared with bupropion.