JULY 2008 PBAC OUTCOMES – POSITIVE RECOMMENDATIONS

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Alendronate sodium with colecalciferol, tablet equivalent to 70 mg alendronic acid with 140 mcg colecalciferol, (Fosamax Plus®) Merck Sharp & Dohme (Australia) Pty Ltd Minor submission	Osteoporosis	To request an Authority Required (Streamlined) listing of a new combination strength of Fosamax Plus, that was deferred from the March 2008 PBAC meeting because the registration was not resolved.	Recommended.

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Amino acid formula with vitamins and minerals without phenylalanine, oral liquid 87 mL, 30, (PKU Cooler 10®), 130 mL, 30, (PKU Cooler 15®), 174 mL, 30, (PKU Cooler 20®) Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, oral liquid 130 mL, 30, (MSUD Express Cooler®) Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, oral liquid, 130 mL, 30, (TYR Cooler®) Amino acid formula with vitamins and minerals without methionine, oral liquid, 130 mL, 30, (HCU Cooler®) Vitaflo Australia Pty Ltd Minor submission	Medical Food	To inform the PBAC of changes to the formulation across the 'Cooler' range of products which include the addition of Omega 3 long chain polyunsaturated fatty acids and improvements in 3 nutrients, calcium, phosphorus and vitamin A. No change to listing is requested.	Recommended.
Atomoxetine hydrochloride, capsule, 80 mg (base), 100 mg (base), (Strattera®) Eli Lilly Australia Pty Ltd Minor submission	Attention Deficit Hyperactivity Disorder	To request an Authority Required listing for two new strengths (80 mg & 100 mg) of atomoxetine for the treatment of a patient with ADHD who meets certain criteria.	Recommended

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Bevacizumab, solution for i.v. infusion 100 mg in 4mL, 400 mg in 16 mL (Avastin®) Roche Products Pty Ltd Minor submission	Colorectal cancer	Metastatic colorectal cancer, in combination with chemotherapy, in a previously untreated patient.	Recommended on basis of high but acceptable cost-effectiveness.
Bortezomib, powder for injection, 3.5 mg (solvent required), (Velcade®) Myeloma Scientific Advisory Group of Myeloma Australia Minor submission	Multiple myeloma	To request the addition of cyclophosphamide for use in combination with bortezomib.	Recommended.
Botulinum toxin type A, lyophilised powder for IM injection, 100 units vial, (Botox®) Allergan Australia Pty Ltd Major submission	Spasticity of the upper limbs	To extend the current section 100 listing to include the treatment of moderate to severe spasticity of the upper limb in adults following a stroke as an adjunct to physical therapy, who meet certain criteria.	Recommended on a cost-minimisation basis with Dysport brand of botulinum toxin.
Botulinum toxin type A purified neurotoxin, lyophilised powder for I.M injection 100 units vial, (Botox®) Allergan Australia Pty Ltd Minor submission	Dynamic equinus foot deformity	To request a continuing criteria for the current listing for botulinum toxin for patients with dynamic equinus foot deformity due to spasticity who have reached 18 years of age and where on-going treatment is required.	Recommended.

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Calcium carbonate, tablet, 1.25 g (equivalent to 600 mg elemental calcium), (Calci-Tabs 600®) AFT Pharmaceuticals Pty Ltd Minor submission	Chronic renal failure.	To request an Authority Required (Streamlined) listing of calcium for the treatment of hyperphosphataemia associated with chronic renal failure.	Recommended.
Dasatinib, tablet, 20 mg, 50 mg, 70 mg, (Sprycel®) Bristol-Myers Squibb Pharmaceuticals Haematology Society of Australia and New Zealand Minor submission	Chronic myeloid leukaemia (CML)	To request changes to the current restriction for dasatinib for CML following the 7 May 2008 Stakeholder meeting	Recommended.
Deferiprone, oral solution, 100 mg per mL, 250 mL, (Ferriprox®) Orphan Australia Pty Ltd Minor submission	Thalassaemia major	To request the addition of a new form of deferiprone under the current Section 100 listing for the treatment of iron overload in a patient with thalassaemia major who meets certain criteria.	Recommended.
Desmopressin acetate, wafer, 120 micrograms, (Minirin® Melt) Ferring Pharmaceuticals Pty Ltd Minor submission	Noctural enuresis	To request the addition of a new form of desmopressin under the current Authority required (Streamlined) listing for the treatment of noctural enuresis in a patient aged 6 years or older, who meets certain criteria.	Recommended on a cost-minimisation basis with desmopressin tablets.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
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, 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	Head and neck cancer	To extend the current Authority Required listing to include induction treatment of locally advanced, squamous cell carcinoma of the head and neck in combination with cisplatin and fluorouracil.	Recommended on the basis of acceptable cost-effectiveness.
Epoprostenol sodium, powder for I.V. infusion, 500 micrograms (base) with 1 vial diluent 50 mL, (Flolan®) GlaxoSmithKline Australia Pty Ltd Minor submission	Pulmonary arterial hypertension	To change the pack for epoprostenol sodium, powder for I.V. infusion, 500 micrograms, with the addition of 1 vial of diluent.	Recommended.
Fludarabine phosphate, solution for i.v injection, 50 mg in 2 ml, fludarabine Ebewe® Interpharma Pty Ltd Minor submission	Anti-cancer drug	The sponsor seeks listing of a new presentation, 50 mg in 2 mL solution for I.V. injection, under the same circumstances as was recommended for the fludarabine dosage forms at the March 2008 PBAC meeting.	Recommended.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Fluorometholone acetate, eye drops 1 mg per mL (0.1%), 5 mL, (Flucon®), (FML Liquidfilm®) Optometrists Association Australia Minor submission	Anti-inflammatory	To request fluorometholone acetate 0.1% be added to the Optometric PBS Schedule.	Recommended.
Glaucoma treatment eye drops (as per current Schedule of Pharmaceutical Benefits with the exception of apraclonidine eye drops). Optometrists Association Australia Minor submission	Glaucoma	To request anti-glaucoma medications be included in the Optometric PBS Schedule	Recommended.
Glucose indicator-blood, electrode strips, 25, 50, 100 on-call plus® Prohealth Asia Pacific Pty Ltd Minor submission	Test strip	Listing of an additional brand of test strips.	Recommended.
Granisetron hydrochloride, tablet, 2mg (base), concentrated injection 3 mg (base) in 3 mL, (Kytril®) Medicare Australia Minor submission	Anti-nauseant	To clarify the intent of the restriction so that use is within 48 hours of chemotherapy and maximum quantities are limited to 5-7 days per chemotherapy cycle.	Recommended.

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Human rotavirus (live attenuated oral vaccine), oral suspension, 1.5 mL in an oral applicator, (Rotarix®) GlaxoSmithKline Pty Ltd Minor submission	Vaccine	To request listing of a new liquid formulation under the National Immunisation Program (NIP).	Recommended.
Imatinib, tablet (as mesylate), 100 mg, 400 mg, (Glivec®) Medicare Australia Minor submission	Metastatic or unresectable malignant gastrointestinal stromal tumour (GIST)	To amend the NOTE from 'No applications for increased maximum quantities and /or repeats will be authorised' from the restriction for GIST to 'No applications for increased repeats will be authorised' to allow larger quantities of 100 mg tablets to be authorised. Medicare Australia will continue to restrict the maximum daily dose to 600 mg.	Recommended
Influenza vaccine Australian Technical Advisory Group on Immunisation (ATAGI) Minor submission	Vaccine	To advise PBAC on moving the current PBS listing for influenza vaccine for use in high risk individuals from the PBS to the National Immunisation Program (NIP).	Recommended for inclusion on NIP.
Insulin glulisine, injections (human analogue) 100 units per mL, 10 mL, (Apidra®) Sanofi-Aventis Australia Pty Ltd Minor submission	Diabetes	To request a Section 85 listing for a new presentation, a 10 mL injection vial, for insulin glulisine	Recommended.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Lopinavir with ritonavir, tablet, 100 mg-25 mg, (Kaletra®) Abbott Australasia Pty Ltd Minor submission	HIV-1 infection	To request listing of a new strength (100 mg/25 mg) lopinavir and ritonavir under the current Section 100 listing conditions for the treatment of HIV-1 infection.	Recommended.
Measles, Mumps, Rubella and Varicella Vaccine, powder for injection vial with diluent syringe, 0.5 mL, Priorix-Tetra® GlaxoSmithKline Australia Ltd Minor submission	Vaccine	To consider advice from ATAGI regarding the scheduling of the combined MMRV vaccine on the NIP.	Previous recommendations regarding scheduling of MMR and MMRV vaccines on NIP altered in line with ATAGI advice. New recommendation is that MMR is given at 12 months of age and MMRV at 18 months of age.
Mesalazine, sachet containing granules, 1.5 g per sachet, (Salofalk®) Orphan Australia Pty Ltd Minor submission	Ulcerative colitis	To request an Authority Required (Streamlined) listing of a new strength of mesalazine granules for the treatment of ulcerative colitis in a patient who meets certain criteria.	Recommended.
Methoxyflurane, solution, 1 x 3 mL plus inhaler, (Penthrox®) Medical Developments International Ltd Major submission	Pain in wound dressing	Authority Required for the relief of pain in wound dressings or trauma in patients aged 2-18 years and in an Aboriginal or Torres Strait Islander where alternate treatments are unsuitable.	Recommended for inclusion in the PBS Doctor's Bag Item List only, on the basis of an acceptable incremental cost per extra paediatric responder with upper limb fracture.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Natalizumab, concentrated solution for IV infusion, 300 mg per 15 ml, (Tysabri®) Biogen Idec Australia Pty Ltd Minor submission	Multiple sclerosis	Add a NOTE which specifies that neurologists prescribing natalizumab must be registered with the Tysabri Australian Prescribing Program, so that the current PBS listing is consistent with the TGA special conditions of registration and to ensure that neurologists are aware of the special conditions for prescribing natalizumab.	Recommended.
Nilotinib, capsule, 200 mg, (Tasigna®) Novartis Pharmaceuticals Australia Pty Limited Haematology Society of Australia and New Zealand Minor submission	Chronic myeloid leukaemia (CML)	To request changes to the current restriction for nilotinib for CML following the 7 May 2008 Stakeholder meeting	Recommended.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Oestradiol & oestradiol with norethisterone acetate, pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 mcg per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 620 mcg-2.7 mg (releasing 50 mcg-140 mcg per 24 hours), (Estalis sesqui 50/140®); pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 mcg per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 510 mcg-4.8 mg (releasing 50 mcg-250 mcg per 24 hours), (Estalis sequi 50/250®) Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Post-menopausal symptoms	To request a change in the description of Estalis 50/140 and 50/250 transdermal patches in the PBS schedule as the oestradiol only patch (Menorest) is being replaced with 'Estradiol 50' which contains less oestradiol per patch (780 micrograms of oestradiol reduced from 4.33 mg). The release rate of oestradiol remains at 50 micrograms per 24 hours.	Recommended.
Ondansetron, tablet, 4 mg and 8 mg, wafer 4 mg and 8 mg, I.V. injection 4 mg in 2 mL and 8 mg in 4 mL (all brands) Medicare Australia Minor submission	Anti-nauseant	To clarify the intent of the restriction so that use is within 48 hours of chemotherapy and maximum quantities are limited to 5-7 days per chemotherapy cycle.	Recommended.

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Paroxetine mesilate, tablet, 20 mg (base), (Paroxetine Generic Health®) Generic Health Pty Ltd Minor submission	Nervous system disorders: - major depressive disorders - obsessive-compulsive disorder - panic disorder	To request listing of a new salt (mesilate) of paroxetine under the current restricted benefit listing conditions, that is bioequivalent with paroxetine hydrochloride.	Recommended
Polyethylene glycol 400 with Propylene glycol, eye drops single dose units, 4mg – 3mg per mL, 28 x 0.7 mL, (Systane® Lubricating Eye Drops Preservative-Free Vials) Optometrists Association Australia Minor submission	Severe dry eye syndrome, including Sjorgen's syndrome	To list lubricant eye drops in the Optometric PBS Schedule.	Recommended.
Protein hydrolysate formula with medium chain triglycerides, compound powder, 450 g, (Pepti-Junior Gold®) Nutricia Australia Pty Ltd Minor submission	Food - for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years	To request listing of a new upgraded formulation to replace the existing Pepti-Junior which will include LCPs and nucleotides.	Recommended
Quetiapine fumarate, modified release tablet, 50 mg, 200 mg, 300 mg, 400 mg, (Seroquel XR®) AstraZeneca Pty Ltd Minor submission	Schizophrenia	To request an Authority required (Streamlined) listing for schizophrenia for a new formulation of quetiapine fumarate and to address the PBAC's concerns from the March 2008 meeting regarding potential for confusion and the clinical need of the extended release formulation.	Recommended

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Repeat prescription requirements for patients with chronic conditions 2008/2009 Budget Initiative Minor submission	Various	To allow patients with chronic conditions who are being cared for under a GP Management Plan or Team Care Plan, to receive up to 12 months supply of some medications in accordance with their doctor's clinical judgement.	PBAC recommended a list of drugs for which a 12-month supply would be suitable.
Ribavirin and Peginterferon alfa-2b, tablets 200 mg and injection pen containing powder, 50 mcg, 80 mcg, 100 mcg, 120 mcg & 150 mcg, (Pegatron®) AND Peginterferon alfa-2b, powder for injection with diluent in single use injection pen, 50 mcg, 80 mcg, 100 mcg, 120 mcg & 150 mcg, (PEG-Intron Redipen ®) Schering-Plough Pty Ltd Major submission	Hepatitis C	To extend the current criteria for Pegatron and PEG-Intron for chronic hepatitis C to include retreatment of treatment failures.	Recommended on the basis of acceptable cost-effectiveness compared with usual standard care.
Ribavirin and peginterferon alfa-2b, pack containing 196 capsules ribavirin 200 mg capsules and 4 single use injections pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent, (Pegatron®) Schering-Plough Pty Ltd Minor submission	Chronic hepatitis C	To request listing of an additional strength of Pegatron under the current Section 100 listing conditions for the treatment of chronic hepatitis C.	Recommended

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Risedronate sodium, tablet, 5 mg (Actonel®), and 35 mg (Actonel Once-a-week®), Risedronate sodium and calcium carbonate, pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), (Actonel Combi®) Sanofi-Aventis Australia Pty Ltd Major submission	Osteoporosis	To extend the current Authority Required (Streamlined) listing to include the prevention and treatment of corticosteroid-induced osteoporosis in a patient on long term (≥ 3 months), high dose (≥ 7.5 mg/day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density T score of ≤-1.5.	Recommended on the basis of an acceptable, although uncertain cost effectiveness ratio in the context of a high and unmet clinical need.
Risperidone, powder for I.M. injections 25mg, 37.5 mg, 50 mg (modified release) with 2 mL diluent in pre-filled syringe, (Risperdal Consta®) Janssen-Cilag Pty Ltd Minor submission	Antipsychotic (behavioural disturbances)	To request listing of new pack that contains an additional 21 gauge, 1-inch Needle Pro® needle for deltoid muscle site injection. The new pack will also contain the current 20 G needle for gluteal administration.	Recommended.
Rituximab, solution for I.V 500 mg in 50 mL, (Mabthera®) Roche Products Pty Ltd Minor submission	Rheumatoid arthritis	To request changes to the restriction wording for rituximab to include use in a patient with RA who has experienced intolerance to at least one tumour necrosis factor antagonist (anti-TNFs).	Recommended.

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Rotigotine, transdermal patch releasing approximately 2 mg per 24 hours, (Neupro 2 mg®); transdermal patch releasing approximately 4 mg per 24 hours, (Neupro 4 mg®); transdermal patch releasing approximately 6 mg per 24 hours, (Neupro 6 mg®); transdermal patch releasing approximately 8 mg per 24 hours, (Neupro 8 mg®) UCB Australia Pty Ltd Minor submission	Parkinson disease	Restricted benefit listing for the treatment of advanced Parkinson disease as adjunctive therapy in patients being treated with levodopa-decarboxylase inhibitor combinations.	The PBAC recommended listing on the basis of non-inferiority to cabergoline in advanced Parkinson disease.
Sevelamer hydrochloride, tablet, 800 mg, (Renagel®) Genzyme Australasia Pty Ltd Minor submission	Chronic kidney disease	To amend the current Section 85 and the section 100 restrictions to improve their clarity.	Recommended.
Sorafenib, tablet, 200 mg, (Nexavar®) Bayer HealthCare Bayer Schering Pharma Major submission	Liver cancer	Authority Required for the treatment of advanced hepatocellular carcinoma patients with unresectable disease.	The PBAC recommended listing on the basis of high but acceptable cost-effectiveness against best supportive care.

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Sunitinib malate 12.5 mg, 25 mg and 50 mg (Sutent®) Pfizer Australia Pty Ltd Minor submission	Renal cell carcinoma	Authority Required listing for advanced/metastatic renal cell carcinoma.	The PBAC recommended listing on the basis of acceptable cost-effectiveness compared with best supportive care.
Telbivudine, tablet, 600 mg, (Sebivo®) Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Chronic hepatitis B	Section 100 listing for chronic hepatitis B HBeAg-negative patients.	The PBAC recommended extending the current listing on a cost-minimisation basis compared to lamivudine, taking into account the lower rates of resistance reported for telbivudine.
Thyrotropin Alfa, powder for injection 0.9 mg, 2, (Thyrogen®) Genzyme Australasia Pty Ltd Minor submission	Anterior pituitary hormone (used in post thyroidectomy)	Request removal of 'adult aged 18 years or older' from the current restriction wording.	The PBAC recommended the amendment to the current listing wording as requested.
Thyrotropin Alfa, powder for injection 0.9 mg, 2, (Thyrogen®) Genzyme Australasia Pty Ltd Minor submission	Anterior pituitary hormone (used in post thyroidectomy)	Request removal of the restriction to one treatment in a patient's lifetime from the current restriction wording to allow patients who may need a second ablation to access the drug as a pharmaceutical benefit item.	The PBAC recommended the amendment to the current listing wording as requested.

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Thyroxine sodium, tablet equivalent to 75 micrograms anhydrous thyroxine sodium, (Oroxine®, Eutroxsig®), Sigma Pharmaceuticals Limited Minor submission	Thyroid hormone (replacement therapy for hypothyroid patients)	To request a Section 85 listing for a new strength of thyroxine tablet.	Recommended.
Tramadol hydrochloride, tablet, 100 mg, 200 mg, 300 mg (sustained release), (Durotram® XR), iNova Pharmaceuticals (Australia) Pty Ltd Minor submission	Pain	Restricted Benefit listing for pain where aspirin and/or paracetamol alone are inappropriate or have failed.	The PBAC recommended listing on a cost-minimisation basis with tramadol sustained release preparations at the same price per mg and under the same circumstances as for the tramadol sustained release preparations. The PBAC also recommended listing in the dental section.
Tropisetron hydrochloride, capsule, 5 mg (base), I.V. injection, 5 mg (base) in 5 mL, (Navoban®) Medicare Australia Minor submission	Anti-nauseant	To clarify the intent of the restriction so that use is within 48 hours of chemotherapy and maximum quantities are limited to 5-7 days per chemotherapy cycle.	Recommended.
Valsartan, tablet, 320 mg, (Diovan®) Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Hypertension	To request a Section 85 unrestricted benefit listing for a new strength of valsartan tablet for the treatment of hypertension.	Recommended on a cost minimisation basis with irbesartan 300 mg, and consistent with the March 2008 PBAC recommendation for valsartan 40 mg, 80 mg and 160 mg tablets.

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Valsartan with amlodipine besylate, tablet, 80 mg-5 mg, 160 mg-5 mg, 160 mg-10 mg, (Exforge®) Novartis Pharmaceuticals Australia Pty Ltd Major submission	Blood pressure	Restricted benefit for the treatment of hypertension in patients who are not adequately controlled with either amlodipine or valsartan monotherapy.	The PBAC recommended listing on a cost-minimisation basis against the individual components.
Valsartan with hydrochlorothiazide, tablet, 80 mg-12.5 mg, 160 mg-12.5 mg, 160 mg-25 mg, (Co-Diovan®) Novartis Pharmaceuticals Australia Pty Ltd Major submission	Blood pressure	Restricted benefit for the treatment of hypertension in patients who are not adequately controlled with either hydrochlorothiazide or valsartan monotherapy.	The PBAC recommended listing on a cost-minimisation basis against the individual components.
Valsartan, tablet, 320 mg, (Diovan®) Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Blood pressure	Unrestricted benefit listing for a new strength of valsartan tablet for the treatment of hypertension.	The PBAC recommended listing on a cost minimisation basis with irbesartan 300 mg, consistent with the March 2008 PBAC recommendation for valsartan 40 mg, 80 mg and 160 mg tablets.
Zoledronic acid, solution for I.V infusion, 5 mg in 100 mL, (Aclasta®) Novartis Pharmaceuticals Australia Pty Ltd Major submission	Osteoporosis	Authority Required for the treatment of established osteoporosis in a patient with a hip fracture due to minimal trauma and secondary prevention of osteoporotic fractures in post-menopausal women with other minimal trauma fractures	The PBAC recommended listing on a cost-minimisation basis against alendronate.