PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2008 PBAC MEETING

Closing date for consumer comments 8 October 2008

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or National Immunisation Program.

The PBAC agenda consists of the following:
1 Minutes of Previous Meeting
2 Chairman's report (verbal)
3 Matters arising from the minutes
4 Matters arising/outstanding
5 New drug applications
6 Requests for changes to listings
7 Resubmissions
8 Pricing Matters
9 Matters relating to PBS review
10 Subcommittee and Working Party reports
11 Other business
12 Correspondence
13 Further information
14 Late papers
15 Tabled papers

Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and re-submissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.

Pharmaceutical benefits listed in the Schedule fall into three broad categories:
Unrestricted benefits – have no restrictions on their therapeutic uses;
Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and
Authority required benefits – Authority required benefits fall into two categories:

- *Authority required benefits* require prior approval from Medicare Australia or the DVA (noted as **Authority required**)

Authority required (STREAMLINED) benefits do not require prior approval from Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as **Authority required (STREAMLINED)**).

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Submission type *(new drug application, changes to listings, resubmissions)*	**Drug Name, form(s), strength(s) and Sponsor** *(Drug name, form, strength, Trade name®, Sponsor)*	**Drug Type and Use** *(What is the drug used to treat?)*	**Purpose of Submission** *(Includes type of listing requested (unrestricted, restricted benefit, authority required) and summary of restriction)*
New application	Amino Acid Formula with Vitamins and Minerals without Phenylalanine, oral liquid 62.5 mL, Lophlex LQ 10®, Nutricia Australia Pty Limited	Medicinal food	Restricted Benefit listing for Phenylketonuria (PKU).
New application	Amino Acid Formula, excluding Phenylalanine and Tyrosine, with Fat, Carbohydrate, Vitamins, Minerals and Trace Elements, sachets, 29 g, TYR Anamix Junior®, Nutricia Australia Pty Limited	Medicinal food	Restricted Benefit listing for use in the dietary management of tyrosinaemia.
New application	Amino Acid Formula, excluding Phenylalanine, with Fat, Carbohydrate, Vitamins, Minerals and Trace Elements and supplemented with Docosahexanoic Acid, oral liquid 125 mL, PKU Anamix Junior LQ®, Nutricia Australia Pty Limited	Medicinal food	Restricted Benefit listing for use in the dietary management of phenylketonuria.
Change to listing	Botulinum toxin type A, vial, powder for IM injection, 100 units, Botox®, Allergan Australia Pty Ltd	Spasticity of the upper limb of children with cerebral palsy	To extend the current Section 100 listing (Botulinum Toxin Program) to include the treatment of moderate to severe spasticity of the upper limbs of children (2 years of age or older) with cerebral palsy.
Change to listing	Capecitabine, tablet, 150 mg, 500 mg, Xeloda®, Roche Products Pty Ltd	Anti-cancer drug	To extend the current Authority Required listing for use in combination with oxaliplatin for the treatment of patients with metastatic colorectal cancer.
Re-submission	Cetuximab, vial, solution for infusion, 2 mg/mL 50 mL, 5 mg/mL 20 mL, 5 mg/mL 100 mL, Erbitux®, Merck Serono Australia Pty Ltd	Anti-cancer drug	Authority Required listing for the treatment of metastatic colorectal cancer following failure of capecitabine, irinotecan and failure of or intolerance to oxaliplatin.
New drug application	Clopidogrel 75 mg with aspirin 100 mg, tablet, CoPlavix®, DuoCover®, Sanofi-aventis, Bristol-Myers Squibb Australia Pty Ltd	Anticoagulant combination	To request an Authority Required (STREAMLINED) listing of a combination product for the treatment of acute coronary syndrome.

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New drug application	Desvenlafaxine, tablet extended release, 50 mg, 100 mg, Pristiq®, Wyeth Australia Pty Limited	Antidepressant	Restricted Benefit listing for major depressive disorders.
Resubmission	Dornase alfa, solution for inhalation 2.5 mg (2,500 units) in 2.5 mL, Pulmozyme®, Roche Products Pty Ltd	Helps manage the respiratory complications of cystic fibrosis	Seeks changes to the current restriction wording to include use in patients aged < 5 years and the inclusion of grandfather clauses.
Change to listing	Efalizumab, injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent, 1.3mL, Raptiva®, Merck Serono Australia Pty Ltd	Psoriasis	To extend the current Authority Required listing of the initial treatment phase with PASI assessment for chronic plaque psoriasis from 12 to 24 weeks.
Change to listing	Escitalopram, oral solution, 10 mg per mL, Lexapro®, Lundbeck Australia Pty Ltd	Mood disorders	To list a new formulation for moderate to severe generalised anxiety disorder (GAD) and moderate to severe social anxiety disorder (SAD).
New drug application	Esomeprazole, sachet containing granules for oral suspension, 10 mg per sachet, Nexium®, AstraZeneca Pty Ltd	Ulcer/reflux	To list a new dosage form.
New application	Essential amino acids formula with vitamins and minerals, Sachets 12.5 g, EAA Supplement®, Vitaflo Australia Pty Ltd	Medicinal food	Restricted Benefit listing for use in the dietary management of urea cycle disorders (UCDs) and other very rare conditions that require a very low protein diet.
Resubmission	Exenatide, injection, 5 micrograms/ 20 microlitres, 10 micrograms/ 40 microlitres, Byetta®, Eli Lilly Australia Pty Limited	Type 2 diabetes	Authority Required listing as combination therapy in type 2 diabetes mellitus.
New drug application	Hydromorphone hydrochloride, tablet, 8 mg, 16 mg, 32 mg, 64 mg, Jurnista®, Janssen-Cilag Pty Ltd	Pain reliever	Restricted Benefit and dental listing for chronic severe disabling pain not responding to non-narcotic analgesics.
Resubmission	Ibandronic acid, tablet, 50 mg, Bondronat®, Hospira Pty Ltd	Reduce bone pain and risk of fracture	Restricted benefit listing for treatment of patients with bone metastases from breast cancer.
Resubmission	Lanthanum carbonate, tablet, 500 mg, 750 mg, 1000 mg, Fosrenol®, Shire Australia Pty Ltd	Phosphate binder	Section 100 Authority Required (initiation and stabilisation) and Section 85 Authority Required (maintenance) for the management of hyperphosphataemia (high level of phosphate in blood) in patients with chronic kidney disease on dialysis.

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Resubmission	Lenalidomide, capsule, 5 mg, 10 mg, 15 mg, 25 mg, Revlimid®, Celgene Pty Ltd	Multiple myeloma	Section 100 Authority Required for treatment in combination with dexamethasone of patients with multiple myeloma who have progressive disease and for whom thalidomide therapy has failed.
Change to listing	Levetiracetam, tablet, 250 mg, 500 mg, 1000 mg, oral solution, 100 mg/mL, Keppra®, UCB Australia Pty Ltd	Anti-epileptic	Authority required for treatment of primary generalised tonic clonic seizures initially as add-on therapy and treatment of generalised myoclonic seizures initially as add-on therapy.
New drug application	Maraviroc, tablet, 150 mg, 300 mg, Celsentri®, Pfizer Pty Limited	Human Immunodeficiency Virus (HIV) infection	Section 100 Authority Required in combination with other antiretrovirals, for the treatment of antiretroviral experienced adult patients infected with CCR5-tropic HIV-1.
Change to listing	Modafinil, tablet, 100 mg, Modavigil®, CSL Limited	Promotes wakefulness	Authority required for the treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy who meet specified criteria.
New application	Modified long chain amylopectin, sachet, 60 g providing 50 g of Glycosade, Glycosade®, Vitaflo Australia Pty Ltd	Medicinal food	Restricted Benefit listing for use in the management of glycogen storage disease (GSD).
New drug application	Oseltamivir, capsule, 75 mg, powder for solution, 12 mg/mL, Tamiflu®, Roche Products Pty Ltd	Anti-viral agent to treat influenza	Restricted benefit listing for the treatment of infections due to influenza A and B viruses in adults and children aged one year and older. Treatment should commence as soon as possible, but no later than 48 hours after the onset of the initial symptoms of infection.
Resubmission	Oxybutynin transdermal drug delivery system, 36 mg (approx 3.9 mg per 24 hours), Oxytrol®, Hospira Pty Ltd	Relaxes wall of bladder	Restricted benefit for treatment of urge urinary incontinence or urgency due to detrusor instability in a patient who cannot tolerate oral oxybutynin or propantheline.
New drug application	Oxycodone hydrochloride, tablet, 15 mg and 30 mg (controlled release), OxyContin®, Mundipharma Pty Ltd	Strong pain reliever	To add two new strengths to the current listing.
New drug application	Paclitaxel, injection suspension vial, 100 mg, Abraxane®, Abraxis BioScience Australia Pty Ltd	Anti-cancer drug	Authority Required listing for advanced breast cancer after failure of prior therapy which includes an anthracycline.

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New drug application	Pancreatic extract, capsule providing not less than 40,000 BP units of lipase activity, Creon®, Solvay Biosciences Pty Ltd	Enzyme replacement used in conditions such as cystic fibrosis and chronic pancreatitis.	To add a new strength to the current listing.
New drug application	Panitumumab, concentrated solution for infusion, 20 mg/mL, Vectibix®, Amgen Australia Pty Ltd	Monoclonal antibody	Authority required for the treatment of a patient with metastatic colorectal cancer that meets specified criteria and who has failed treatment with a fluoropyrimidine, irinotecan and oxaliplatin.
Change to listing	Pegfilgrastim, injection, 6 mg in 0.6 mL, single use pre-filled syringe, Neulasta®, Amgen Australia Pty Ltd	Helps the immune system recover from the effect of chemotherapy in cancer patients	To request an additional Section 100 Authority Required listing as primary prophylaxis of neutropenic complications in patients with chronic lymphocytic leukaemia treated with fludarabine and cyclophosphamide.
New application	Phenylalanine with Carbohydrate, sachets, 4g containing 50 mg Phenylalanine, Phenylalanine Amino Acid Supplement®, Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted Benefit listing for use in the dietary management of tyrosinaemia.
Review	Pioglitazone, tablet., 15 mg (base), 30 mg (base), 45 mg (base), Actos®, Eli Lilly Australia Pty Limited	Type 2 diabetes	To review the appropriateness of the current PBS listings for pioglitazone in view of recent regulatory action in respect of rosiglitazone.
New drug application	Poly-L-lactic acid, vial of dry powder to be reconstituted, 150 mg, Sculptra®, Sanofi-Aventis Australia Pty Limited	Injectable polymer to restore lost facial volume	Authority Required for the treatment of facial lipoatrophy caused by antiretroviral therapy in HIV positive patients.
Resubmission	Pramipexole, tablet, 125 micrograms, 250 micrograms, Sifrol®, Boehringer Ingelheim Pty Limited	For the treatment of Parkinson disease and of Restless Legs Syndrome symptoms	Restricted Benefit for the treatment of severe idiopathic Restless Legs Syndrome (RLS) in a patient who manifests certain diagnostic criteria and who has a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score of greater than or equal to 21 points.
Resubmission	Tamsulosin, tablet, 0.4 mg, Flomaxtra®, CSL Limited	Enlarged prostate	Restricted benefit for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.
New drug application	Telmisartan with hydrochlorothiazide, tablets, 80 mg/25 mg, Micardis Plus®, Boehringer Ingelheim Pty Limited	Hypertension	To request listing of a new strength.

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Change to listing	Tenofovir disoproxil fumarate, tablet, 300 mg, Viread®, Gilead Sciences Pty Ltd	Chronic hepatitis B	Section 100 Authority Required for treatment-of chronic hepatitis B patients who satisfy certain criteria.
Resubmission	Teriparatide, injection, 250 microgram/ mL, Forteo®, Eli Lilly Australia Pty Limited	Osteoporosis	Authority required for the treatment as the sole PBS-subsidised agent for patients with steroid-induced osteoporosis who have a very high risk of fracture. Authority Required for treatment as the sole PBS-subsidised agent for patients with severe, established osteoporosis who have a very high risk of fracture where other agents would be considered unsuitable.
New drug application	Tobramycin injection 500 mg in 5 mL, Tobra-Day®, Phebra Pty Ltd	Antibiotic	To request a higher strength as a Restricted Benefit for the treatment of *Pseudomonas aeruginosa* infections in patients with cystic fibrosis.
Resubmission	Trandolapril 2 mg with verapamil 180 mg (sustained release), tablet, Tarka®, Abbott Australasia Pty Ltd	Hypertension	To request a lower strength of the existing 4 mg-240 mg tablet to allow patients to be commenced on a lower strength combination.
Review	Trastuzumab, powder for I.V. infusion, 150 mg, Herceptin®, Roche Products Pty Ltd	Metastatic breast cancer	To review the clinical and cost-effectiveness of trastuzumab for metastatic breast cancer.
New application	Triglycerides, medium chain, sachets, 16 g containing 10 g MCT fats, MCT Pro-Cal®, Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted Benefit listing for use in the dietary management of fat malabsorption, long chain fatty acid oxidation disorders (FAOD), Type 1 hyperlipidaemia, chylothorax and management of malnutrition.
New drug application	Valsartan with hydrochlorothiazide, tablet, 320 mg/12.5 mg, 320 mg/25 mg, Co-Diovan®, Novartis Pharmaceuticals Australia Pty Ltd	Hypertension	To request the listing of two additional strengths.
New application	Whey Protein Formula supplemented with Amino Acids, Vitamins and Minerals, and low in Protein, Phosphate, Potassium and Lactose supplemented with long chain polyunsaturated fatty acids (LCPs), sachets, 100 g, RenaStart®, Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted Benefit listing for use in the dietary treatment of infants and children up to the age of 10 years with chronic renal failure (CRF) and those requiring dialysis.

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Change to listing	Ziprasidone, capsule, 20 mg, 40 mg, 60 mg, 80 mg, Zeldox®, Pfizer Pty Limited	Bipolar disorder	Authority Required (STREAMLINED) as monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder.
Change to listing	Zoledronic acid, solution for infusion, 5 mg in 100 mL, Aclasta®, Novartis Pharmaceuticals Australia Pty Ltd	Osteoporosis	Authority required (STREAMLINED) for treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in women aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.