

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

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)**).

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

Submission type <i>(new drug application, changes to listings, resubmissions)</i>	Drug Name, form(s), strength(s) and Sponsor <i>(Drug name, form, strength, Trade name[®], Sponsor)</i>	Drug Type and Use <i>(What is the drug used to treat?)</i>	Listing requested by Sponsor / Purpose of Submission <i>(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased)</i>
Re-submission	Adalimumab, Injection 40 mg in 0.8 mL, pre-filled pen and pre-filled syringe, Humira [®] , Abbott Australasia Pty Ltd	Chronic plaque psoriasis	To extend the current authority required listing to include the treatment of patients with severe chronic plaque psoriasis.
Re-submission	Alglucosidase alfa, Powder for IV infusion, 50 mg (solvent required), Myozyme [®] , Genzyme Australasia Pty Ltd	Pompe disease	To extend the indication on the Life Saving Drug Program (LSDP) to include the treatment of a patient with late onset Pompe disease who meets certain criteria.
New drug application	Amino acid formula with vitamins and minerals without Lysine and low in tryptophan, Sachets, 20 g, 30, GA Gel [®] , Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for the dietary management of a patient with Glutaric Aciduria Type 1.
New drug application	Arginine with carbohydrate, Sachet, 4g (containing 500 mg Arginine), 30, Arginine Amino Acid Supplement [®] , Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for the dietary management of a patient with urea cycle disorders excluding arginase deficiency and other inborn errors of metabolism.
New drug application	Arsenic trioxide, Solution for I.V. infusion, 10 mg in 10 mL, Phenasen [®] , Phebra Pty Ltd	Acute Promyelocytic Leukaemia	Authority required listing for relapsed or refractory acute promyelocytic leukaemia (APL) in patients who meet certain criteria.
New drug application	Atovaquone with proguanil hydrochloride, Tablet, 250 mg-100 mg (base), Malarone [®] , GlaxoSmithKline Australia Pty Ltd	Anti-malarial	Authority required (STREAMLINED) listing for the treatment of suspected or confirmed Plasmodium falciparum malaria in adults and children aged 3 years and older.
New drug application	Bimatoprost with timolol maleate, Eye drops, 0.3 mg–5 mg (base) per mL, (0.03%–0.5%), 3 mL, Ganfort [®] , Allergan Australia Pty Ltd	Anti-glaucoma	Restricted benefit listing for open-angle glaucoma not adequately controlled with timolol maleate 0.5%, latanoprost or bimatoprost eye drops.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

New drug application	Cefuroxime axetil, Powder for oral liquid, 250 mg (base) in 5 mL, Zinnat [®] , GlaxoSmithKline Australia Pty Ltd	Antibiotic	Unrestricted benefit listing.
Re-submission	Cetuximab, Solution for I.V. infusion 100 mg in 20 mL, 100 mg in 50 mL, and 500 mg in 100mL. Erbitux [®] , Merck Serono Australia Pty Ltd	Anti-cancer	Authority required listing for third-line treatment of a patient with K-Ras wild type metastatic colorectal cancer in combination with irinotecan.
New drug application	Clindamycin (phosphate) with benzoyl peroxide, Gel, 10 mg (base) - 50 mg per gm (1% – 5%), 25 gm, Duac [®] Once Daily Gel, Stiefel Laboratories Pty Ltd	Topical anti-acne treatment	Restricted benefit listing for treatment of moderate acne vulgaris in patients who meet certain criteria.
Change to listing	Clostridium botulinum type A toxin–haemagglutinin complex, Lyophilised powder for I.M. injection 500 units, Dysport [®] , Ipsen Pty Ltd	Anti-spasticity injection that allows the muscle to relax	To change the current Section 100 initiation criteria for post-stroke spasticity of the upper limb from 3-6 months post stroke to 3 months post stroke.
New drug application	Dabigatran etexilate mesilate, Capsule, 75 mg, 110 mg, (base), Pradaxa [®] , Boehringer Ingelheim Pty Limited	Anticoagulant	Restricted benefit listing for prevention of venous thromboembolic events (VTEs) in adult patients undergoing total hip replacement surgery.
Change to listing	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, Taxotere [®] 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	Anti-cancer	To request removal of the note from the current restriction for docetaxel for metastatic carcinoma of the prostate which limits treatment to a maximum of 10 cycles.
Re-submission	Eculizumab, Solution concentrate for I.V. infusion, 300 mg in 30 mL, Soliris [®] , Alexion Pharmaceuticals Australasia Pty Ltd	Paroxysmal Nocturnal Haemoglobinuria	Section 100 listing, or listing under the Life Saving Drug Program (LSDP), for the treatment of a patient with paroxysmal nocturnal haemoglobinuria (PNH) to reduce haemolysis.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

Change to listing	Epoprostenol sodium, Powder for I.V. infusion 500 micrograms (base) with diluent, Flolan [®] , GlaxoSmithKline Australia Pty Ltd	Pulmonary Arterial Hypertension	To change the current Section 100 listing to allow only second line use in patients with WHO Class III primary pulmonary hypertension (PPH). To retain first line use for patients with WHO class IV PPH.
Re-submission	Essential amino acid formula without phenylalanine, with carbohydrate, fat, vitamins, minerals and trace elements, Sachets, 15.8 g, 40, Lanaflex [®] , Nutricia Australia Pty Ltd	Medicinal food	Restricted benefit listing for the dietary management of adult patients with proven phenylketonuria (PKU).
Re-submission	Etanercept, Injection set containing 4 vials powder for injection 25 mg, 50 mg; and 4 pre-filled syringes solvent 1 mL; Injections 50 mg in 1 mL single use pre-filled syringes, 4, Enbrel [®] , Wyeth Australia Pty Ltd	Chronic plaque psoriasis	To change the current authority required restriction for the treatment of severe chronic plaque psoriasis as follows to (a) continuous rather than intermittent treatment, and (b) initial treatment period of 24 weeks.
New drug application	Etravirine, Tablet, 100 mg, Intelence [®] , Janssen-Cilag Australia Pty Ltd	Human Immunodeficiency Virus (HIV) infection	Section 100 listing for treatment in combination with other antiretroviral agents of HIV infection in patients who meet certain criteria and who have failed previous treatment with or have resistance to three different antiretroviral regimens.
New drug application	Ezetimibe with simvastatin, Tablet, 10 mg – 20 mg, Vytorin [®] , Merck Sharp & Dohme	Lipid-lowering drug	Authority required (STREAMLINED) listing to include treatment in conjunction with dietary therapy and exercise in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) at a daily dose of <u>20 mg or greater</u> and who meet the criteria of the <i>General Statement for Lipid-Lowering Drugs Prescribed as Pharmaceutical Benefits</i> .
New drug application	Glucose, I.V. infusion (5%), 100 mL, 250 mL and 500 mL, B Braun brand, B Braun Australia Pty Ltd	Intravenous nutrition	Unrestricted benefit listing under solutions for parenteral nutrition.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

New drug application	High fat, low protein formula with low carbohydrate, and vitamins, minerals and trace elements, Powder, 300 g, Ketocal [®] , Nutricia Australia Pty Ltd	Medicinal food	Restricted benefit listing for the dietary management of a patient with intractable seizures requiring treatment ketogenic diet (KD); Glucose Transport Protein Defects and Pyruvate Dehydrogenase Deficiency.
Change to listing	Iloprost trometamol, Solution for inhalation 20 micrograms (base) in 2 mL, Ventavis [®] , Bayer Schering Pharma	Pulmonary Arterial Hypertension	To change the current Section 100 listing to allow only second line use in patients with WHO Class III primary pulmonary hypertension (PPH) and class III pulmonary arterial hypertension (PAH) secondary to connective tissue disorder. Retain first line use for patients with drug induced PAH, class IV PPH or class IV PAH secondary to connective tissue disease.
Change to listing	Imatinib, Tablet 100 mg and 400 mg (as mesylate), Glivec [®] , Novartis Pharmaceuticals, Australia Pty Ltd	Anti-cancer	To remove the lifetime maximum of 24 months PBS-treatment from the current restriction for the treatment of a patient with newly diagnosed lymphoblastic leukaemia (ALL) and who meets certain criteria.
New drug application	Isoleucine with carbohydrate, Sachet, 4 g, 30 (containing 1000 mg isoleucine), Isoleucine 1000 Amino Acid Supplement [®] , Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for Maple Syrup Urine Disease (MSUD).
Change to listing	Leuprorelin acetate, Suspension for subcutaneous injection (modified release), 22.5 mg injection set, Eligard [®] 3 month; Suspension for subcutaneous injection (modified release), 30 mg injection set, Eligard [®] 4 month; Suspension for subcutaneous injection (modified release), 45 mg injection set, Eligard [®] 6 month; Suspension for subcutaneous injection (modified release), 7.5 mg injection set, Eligard [®] 1 month, Hospira Pty Ltd	Anti-cancer	To amend current Authority required listing to Authority required (STREAMLINED) for the treatment of a patient with locally advanced or metastatic carcinoma of the prostate who meet certain criteria.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

Re-submission	Levodopa with carbidopa monohydrate, Intestinal gel, 20 mg –5 mg (base) per mL, 100 mL, Duodopa [®] , Solvay Pharmaceuticals	Parkinson disease	Section 100 listing for initial treatment, and section 85 listing for continued treatment, of patients with Parkinson Disease where initial treatment is commenced in a hospital-based Movement Disorder clinic.
New drug application	Methylnaltrexone bromide, Injection, 12 mg in 0.6 mL (base), Relistor [®] , Wyeth Australia Pty Ltd	Laxative	Palliative care listing as an authority required for initial and continuing treatment of opioid-induced constipation in patients who have failed/unable to tolerate laxative therapies.
New drug application	Mupirocin, Nasal ointment, 20 mg (as calcium) per g (2%), 3 g Bactroban [®] , GlaxoSmithKline Australia Pty Ltd	Intranasal antibiotic	Authority required (STREAMLINED) listing for the treatment of nasal colonisation with Staphylococcus aureus in Aboriginal and Torres Strait Islander persons.
Re-submission	Oxybutynin, transdermal patches, 36 mg (releasing approximately 3.9 mg per 24 hours), Oxytrol [®] , Hospira Australia Pty Ltd	Relaxes wall of bladder	Restricted benefit listing for the treatment of a patient with urge urinary incontinence or urgency due to detrusor irritability in a patient who can not tolerate or swallow oral oxybutynin.
Re-submission	Paricalcitol, Solution for I.V. injection, 2 microgram in 1 mL, 5 microgram in 1 mL; Capsule, 1 microgram, 2 microgram, Zemlar [®] , Abbott Australasia Pty Ltd	End-stage kidney disease	Section 100 listing for treatment by a nephrologist of patients with chronic kidney disease (Stage V) receiving dialysis who have secondary hyperparathyroidism.
Change to listing	Pemetrexed disodium, Powder for I.V. infusion 100 mg, 500 mg (base), Alimta [®] , Eli Lilly Australia Pty Limited	Anti-cancer	To extend the current authority required listing to include first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer with non-squamous cell histology (adenocarcinoma and/or large cell carcinoma) in combination with cisplatin.
Re-submission	Poly-L-lactic acid, Powder for intradermal injection, 150 mg, Sculptra [®] , Sanofi-Aventis Australia Pty Ltd	Restores lost facial volume	Authority required listing for the treatment of a patient with facial lipoatrophy caused by antiretroviral therapy in HIV positive patients.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

New drug application	Praziquantel, Tablet, 600 mg, Biltricide [®] , Bayer Health Care Bayer Schering Pharma	Anti-parasitic	Section 85 listing for the treatment of Schistosoma infections due to various types of blood fluke. (Type of listing not specified).
Change to listing	Quetiapine fumarate, Tablet, 25 mg, 100 mg, 200 mg and 300 mg (base), Seroquel [®] , AstraZeneca Pty Ltd	Bipolar disorder	To extend the current authority required (STREAMLINED) listing to include treatment of patients with depressive episodes associated with bipolar disorder.
Change to listing	Quetiapine fumarate, Tablet, 25 mg, 100 mg, 200 mg and 300 mg (base), Seroquel [®] , AstraZeneca Pty Ltd	Bipolar disorder	To extend the current authority required listing to include maintenance treatment of patients with bipolar 1 disorder in combination with a mood stabiliser for the prevention of recurrence of manic, depressive or mixed episodes.
New drug application	Risedronate sodium, Tablet, 150 mg, Actonel Once-a-Month [®] 150 mg, Sanofi-Aventis Australia Pty Ltd	Osteoporosis	Authority required (STREAMLINED) listing for initial and continuing treatment used as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.
New drug application	Rivaroxaban, Tablet, 10 mg, Xarelto [®] , Bayer Australia Limited	Anti-coagulant	To request a dual listing as Authority required (STREAMLINED) and section 100 listing for prevention of venous thromboembolism (VTE) in patients undergoing (i) hip replacement/arthroplasty; (ii) knee replacement/arthroplasty.
New drug application	Sitagliptin with metformin hydrochloride, Tablet 25 mg (as phosphate monohydrate)–500mg, 50 mg (as phosphate monohydrate)–850 mg, and 50 mg (as phosphate monohydrate)–1000 mg, Janumet [®] , Merck Sharp & Dohme (Australia) Pty Ltd	Type 2 diabetes	Authority required (STREAMLINED) listing for patients with Type II diabetes (i) where a combination of metformin and a sulfonylurea is contraindicated or not tolerated; or (ii) who have previously been authorised for treatment with, pioglitazone or rosiglitazone in combination with metformin.
New drug application	Sodium chloride, I.V. infusion (0.9%), 100 mL, 250 mL and 500 mL, B Braun brand, B Braun Australia Pty Ltd	Electrolyte imbalance	Unrestricted benefit listing under solutions affecting the electrolyte balance.
New drug application	Soy lecithin liposome, Eye spray, 10 mg per mL (1.0%), 10 mL, Tears Again [®] , Biorevive Pty Ltd	Dry-eye lubricant	Section 85 listing for the relief of dry eyes.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2009 PBAC MEETING**

Closing date for consumer comments 11 February 2009

New drug application	Temozolomide, Powder for I.V. injection 100 mg, Temodal [®] , Schering Plough Pty Ltd	Anti-cancer	Authority required listing under the current listing criteria as for the capsules but for patients who are unable to take a solid dose form of temozolomide.
Change to listing	Thalidomide, Capsule, 50 mg, Thalidomide Pharmion [®] , Celgene Pty Ltd, Celgene Pty Ltd	Multiple myeloma	To extend the current section 100 listing to include treatment of a patient newly diagnosed with multiple myeloma, or in a patient who is ineligible for treatment with high dose chemotherapy or a stem cell transplant.
New drug application	Valine with carbohydrate, Sachet, 4 g, 30, (containing 1000 mg Valine), Valine 1000 Amino Acid Supplement [®] , Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for Maple Syrup Urine Disease (MSUD).

ADDENDUM TO THE WEB AGENDA

Submission type <i>(new drug application, changes to listings, resubmissions)</i>	Drug Name, form(s), strength(s) and Sponsor <i>(Drug name, form, strength, Trade name[®], Sponsor)</i>	Drug Type and Use <i>(What is the drug used to treat?)</i>	Listing requested by Sponsor / Purpose of Submission <i>(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased)</i>
Review	Clopidogrel hydrogen sulfate, tablet, 75 mg (base), Iscover [®] , Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd; Plavix [®] , Sanofi-Aventis Australia Pty Ltd	Anti-platelet	A review of the cost-effectiveness of clopidogrel in coronary artery stenting.
Review	Imiquimod, cream 50 mg per g (5%), 250 mg single use sachets, 12, Aldara [®] , iNova Pharmaceuticals (Aust) Pty Ltd	Solar keratoses	Report on the Independent Review for imiquimod for the treatment of solar keratoses.