PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2009 PBAC MEETING

Closing date for consumer comments 7 October 2009

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

Submissions are categorised broadly as major or minor:

- *Major:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
- *Minor:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.

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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?)*	**Listing requested by Sponsor / Purpose of Submission** *(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased)*
Change to listing (Minor submission)	Albendazole, tablet, 200 mg, Zentel®, GlaxoSmithKline Australia Pty Ltd.	Helminth (worm) infections	Extend the current Authority Required (STREAMLINED) listing to include treatment of hookworm infection in a refugee or humanitarian entrant or an Aboriginal or a Torres Strait Islander person, and treatment of intestinal Strongyloidiasis in a refugee or humanitarian entrant or an Aboriginal or a Torres Strait Islander person less than 12 years of age.
Re-submission (Major submission)	Alglucosidase alfa, powder for I.V. infusion, 50 mg, Myozyme®, Genzyme Australasia Pty Ltd.	Pompe disease	Re-submission to extend the indication on the Life Saving Drugs Program (LSDP) to include the treatment of a patient with late-onset Pompe disease who meets certain criteria.
Change to listing (Minor submission)	Amino acid formula with vitamins and minerals without lysine and low in tryptophan, infant formula, powder 400 g, XLYS, LOW TRY Analog®, Nutricia Australia Pty Ltd. Amino acid formula with vitamins and minerals without methionine, infant formula, powder 400 g, XMET Analog®, Nutricia Australia Pty Ltd. Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, infant formula, powder 400 g, XMTVI Analog®, Nutricia Australia Pty Ltd. Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, infant formula, powder 400 g, XPhen Tyr Analog®, Nutricia Australia Pty Ltd. Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, infant formula, powder 400 g, MSUD Analog®, Nutricia Australia Pty Ltd.	Medicinal foods	Combined submission for the Analog range of infant formula products. Brand name change and formulation change to include long chain polyunsaturated fatty acids and prebiotic oligosaccharides.

	Amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine, infant formula, powder 400 g, XP Analog LCP®, Nutricia Australia Pty Ltd.		
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without methionine, oral liquid, 125 mL, HCU Anamix Junior LQ®, Nutricia Australia Pty Ltd.	Medicinal food	Restricted Benefit listing for pyridoxine non-responsive homocystinuria.
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, oral liquid, 125 mL, TYR Anamix Junior LQ®, Nutricia Australia Pty Ltd.	Medicinal food	Restricted Benefit listing for tyrosinaemia.
New drug application (Minor submission)	Amino acids, synthetic formula, supplemented with long chain polyunsaturated fatty acids, compound powder 400 g, EleCare LCP®, Abbot Australasia Pty Ltd.	Medicinal food	Authority Required listing for initial and continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae, severe intolerance (not infant colic) to cows' milk protein, and severe intestinal malabsorption including short bowel syndrome, in patients who meet certain criteria.
Change to listing (Major submission)	Aprepitant, pack containing 1 capsule 125 mg and 2 capsules 80 mg, Emend®, Merck Sharp & Dohme (Australia) Pty Ltd.	Anti-nauseant	Extend the current Authority Required listing to include chemotherapy induced nausea and vomiting associated with moderately emetogenic chemotherapy.
Change to listing (Minor submission)	Bicalutamide, tablet, 50 mg, Cosudex®, Astra Zeneca Pty Ltd. Goserelin acetate, subcutaneous implant (long acting) 10.8 mg (base), in pre-filled injection syringe, Zoladex 10.8 Implant®, AstraZeneca Pty Ltd Goserelin acetate and bicalutamide, packs containing 1 subcutaneous implant goserelin 3.6 mg, and 10.8 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg, ZolaCos CP 3.6/50®, ZolaCos CP 10.8/50(28)® and pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 84 tablets bicalutamide 50 mg, ZolaCos CP 10.8/50 (84)®, AstraZeneca Pty Ltd.	Prostate cancer	Combined submission from AstraZeneca requesting Authority Required (STREAMLINED) listings for bicalutamide, goserelin acetate 10.8 mg, and the combination products containing bicalutamide and goserelin acetate.

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Change to listing (Major submission)	Botulinum toxin type A purified neurotoxin complex, lyophilised powder for I.M. injection, 100 units, Botox®, Allergan Australia Pty Ltd.	Excessive sweating	Extend the current Section 100 (Botulinum Toxin Program) listing to include: Option 1: severe primary axillary hyperhidrosis in adult and adolescent patients (> 12 years of age) who meet certain criteria and have failed or are intolerant to topical aluminium chloride hexahydrate. Option 2: treatment of severe primary axillary hyperhidrosis as per Option 1 but includes a measure of spontaneous resting axillary sweat production in the listing criteria.
New drug application (Minor submission)	Candesartan cilexetil with hydrochlorothiazide, tablets, 32 mg-12.5 mg and 32 mg-25mg, Atacand Plus®, AstraZeneca Pty Ltd.	Anti-hypertensive	Restricted Benefit listing for 2 new strengths for treatment of hypertension in patients who are not adequately controlled with candesartan monotherapy.
Re-submission (Major submission)	Dabigatran etexilate mesylate, capsule, 75 mg and 110 mg (base), Pradaxa®, Boehringer-Ingelheim Pty Ltd.	Anti-coagulant	Re-submission for an Authority Required listing for prevention of venous thromboembolic events in patients undergoing total hip replacement (THR) surgery and total knee replacement (TKR) surgery.
Change to listing (Major submission)	Darunavir, tablet, 300 mg (as ethanolate), Prezista®, Janssen-Cilag Pty Ltd.	Human Immunodeficiency Virus (HIV) infection	Replace the current Section 100 (Highly Specialised Drugs Program) listing with: Treatment, in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily, of HIV infection in antiretroviral experienced patients with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. A patient must have failed previous treatment with, or have resistance to, 1 antiretroviral regimen.
Re-submission (Major submission)	Diclofenac sodium with misoprostol, tablet, 50 mg- 200 micrograms, Arthrotec®, Pfizer Australia Pty Ltd.	Non-steroidal anti-inflammatory drug with gastric protectant	Re-submission for an Authority Required (STREAMLINED) listing for osteoarthritis or rheumatoid arthritis in patients who require prophylaxis against NSAID-induced peptic ulcers.

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Change to listing (Major submission)	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.	Anti-cancer drug	Extend the current Authority Required listing to include adjuvant treatment of operable breast cancer in combination with cyclophosphamide.
Re-submission (Minor submission)	Dutasteride, capsule, 0.5 mg, Avodart®, GlaxoSmithKline Australia Pty Ltd.	Enlarged prostate	Re-submission for an Authority Required (STREAMLINED) listing for the treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist.
New drug application (Minor submission)	Essential amino acid formula, powder 200 g, Essential Amino Acid Mix®, Nutricia Australia Pty Ltd.	Medicinal food	Restricted Benefit listing for urea cycle disorders, and gyrate atrophy of the choroid and retina.
New drug application (Major submission)	Everolimus, tablets, 5 mg and 10 mg, Afinitor®, Novartis Pharmaceuticals Australia Pty Ltd.	Anti-cancer drug	Authority Required listing for treatment, as the sole PBS-subsidised therapy, of a patient with Stage IV clear cell variant renal cell carcinoma after failure of treatment with sorafenib or sunitinib.
Change to listing (Minor submission)	Ezetimibe, tablet, 10 mg, Ezetrol®, Merck Sharp & Dohme (Australia) Pty Ltd. Ezetimibe with simvastatin, tablets 10 mg-40 mg and 10 mg-80 mg, Vytorin®, Merck Sharp & Dohme (Australia) Pty Ltd.	High cholesterol and lipid levels	Combined submission from Merck Sharp & Dohme requesting to change the current Authority Required (STREAMLINED) listings for ezetimibe and ezetimibe with simvastatin combination products to Restricted Benefit.
New drug application (Major submission)	Ganirelix, solution for injection, 250 micrograms in 0.5 mL (as acetate), single use pre-filled syringe, Orgalutran®, Schering-Plough Pty Ltd.	Fertility drug	Section 100 (IVF / GIFT Treatment Program) listing for prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.
Change to listing (Minor submission)	Gefitinib, tablet, 250 mg, Iressa®, AstraZeneca Pty Ltd.	Lung cancer	Requests a change to the current Authority Required restriction wording so that the specific method used to detect mutations in the epidermal growth factor receptor (EGFR) gene is not specified, and therefore newer technologies are not excluded.

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New drug application (Minor submission)	Glucose, I.V. infusion, 69.5 mmol (anhydrous) per 250 mL, (5%), 250 mL. Sodium chloride, I.V. infusion, 38.5 mmol per 250 mL, (0.9%), 250 mL	Intravenous nutrition Intravenous electrolyte therapy	Unrestricted listings in the Dental Schedule of the PBS of lower volume products.
Change to listing (Minor submission)	Goserelin acetate, subcutaneous implant 3.6 mg (base) in pre-filled injection syringe, Zoladex Implant®, AstraZeneca Pty Ltd.	Early breast cancer	Extend the current Authority Required listing to include use in early breast cancer in peri- or pre-menopausal women.
New drug application (Minor submission)	Hydromorphone hydrochloride, tablet, 4 mg (modified release), Jurnista®, Janssen-Cilag Pty Ltd.	Analgesic	Restricted Benefit listing in the general and dental schedules, of a new, lower dose.
New drug application (Minor submission)	Ibuprofen, tablet, 800 mg (sustained release), Brufen SR®, Abbott Australasia Pty Ltd.	Non-steroidal anti-inflammatory drug	Request for listing of a new formulation and strength of ibuprofen: 1) Restricted Benefit in the General Schedule for chronic arthropathies (including osteoarthritis) with an inflammatory component and bone pain due to malignant disease; and 2) Authority Required in the Palliative Care Schedule for patients where severe pain is a problem.
Change to listing (Major submission)	Imatinib, tablets, 100 mg and 400 mg (as mesylate), Glivec®, Novartis Pharmaceuticals Australia Pty Ltd.	Anti-cancer drug	Extend the current Authority Required listing to include adjuvant treatment of a patient at high risk of recurrence following complete resection of primary gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining, at a dose not exceeding 400 mg/day for a period of 12 months, who meets certain criteria.
New drug application (Major submission)	Lacosamide, tablets, 50 mg, 100 mg, 150 mg and 200 mg and oral solution 15 mg per mL, 465 mL, Vimpat®, UCB Australia Pty Ltd.	Epilepsy	Authority Required listing for treatment of partial epileptic seizures not controlled satisfactorily by other anti-epileptic drugs in a patient who meets certain criteria.
Re-submission (Major submission)	Maraviroc, tablets 150 mg and 300 mg, Celsentri®, Pfizer Australia Pty Ltd.	Human Immunodeficiency Virus (HIV) infection	Re-submission for a Section 100 (Highly Specialised Drugs Program) listing for treatment, in combination with other antiretrovirals, of an antiretroviral experienced adult patient infected only with CCR5-tropic HIV-1 who meet certain

			criteria.
New drug application (Minor submission)	Mesalazine, tablet 1200 mg (prolonged release), Mezavant®, Shire Australia Pty Ltd.	Ulcerative colitis	Request for a new strength of a prolonged release formulation as an Authority Required (STREAMLINED) listing for ulcerative colitis where hypersensitivity to sulfonamides exists or where intolerance to sulfasalazine exists.
New drug application (Major submission)	Methoxy-polyethylene glycol-epoetin beta, solution for injection, 30 micrograms in 0.3 mL, 50 micrograms in 0.3 mL, 75 micrograms in 0.3 mL, 100 micrograms in 0.3 mL, 120 micrograms in 0.3 mL, 200 micrograms in 0.3 mL and 360 micrograms in 0.6 mL, single use pre-filled syringe, Mircera®, Roche Products Pty Ltd .	Anaemia associated with renal disease	Section 100 (Highly Specialised Drugs Program) listing for treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per litre, where intrinsic renal disease, as assessed by a nephrologist, in the primary cause of the anaemia.
New drug application (Minor submission)	Milk powder – nutrient rich, infant formula powder, 400 g, S-26 Gold Premgro®, Wyeth Australia Pty Ltd.	Medicinal food	Option 1: Authority Required listing for treatment of premature infants born at less than 30 weeks gestation, up to the age of 6 months for whom breast-feeding is not possible. Option 2: As above but for premature infants born at less than 33 weeks gestation.
New drug application (Major submission)	Nebivolol, tablets, 1.25 mg, 5 mg and 10 mg (as hydrochloride), and titration pack containing 42 tablets 1.25 mg and 14 tablets 5 mg, Nebilet®, CSL Limited.	Heart failure	Authority Required (STREAMLINED) listing for moderate to severe heart failure stabilised on conventional therapy which must include an ACE inhibitor if tolerated.
Re-submission (Minor submission)	Nevirapine, oral liquid, 10 mg per mL, 240 mL, Viramune®, Boehringer-Ingelheim Pty Ltd.	Human Immunodeficiency Virus (HIV) infection	Request the PBAC reinstate the rescinded June 2000 recommendation for a Section 100 (Highly Specialised Drugs Program) listing for treatment of HIV infection for use in paediatric patients who meet certain criteria.
New drug application (Major submission)	Omalizumab (rch), powder for injection, 150 mg, Xolair®, Novartis Pharmaceuticals Australia Pty Ltd.	Severe allergic asthma	Option 1: Section 100 (Highly Specialised Drugs Program) Public and Private Hospital Authority Required listing for initial and continuing treatment of uncontrolled severe allergic asthma despite optimised asthma therapy (OAT) in a patient who satisfies certain criteria. Option 2:

			As per option 1 but without oral corticosteroids (OCS) as part of optimised asthma therapy.
Re-submission (Major submission)	Pemetrexed disodium, powder for IV infusion, 100 mg and 500 mg (base), Alimta®, Eli Lilly Australia Pty Ltd.	Anti-cancer drug	Extend the current Authority Required listing to include locally advanced or metastatic non-small-cell lung cancer (NSCLC) with predominantly non-squamous cell histology in combination with cisplatin.
Change to listing (Minor submission)	Quetiapine fumarate, tablets, 25 mg, 100 mg, 200 mg and 300 mg (base), Seroquel®, AstraZeneca Pty Ltd	Bipolar disorder	Extend the current Authority Required (STREAMLINED) listing to include treatment, for up to 6 months, of an episode of acute mania associated with bipolar 1 disorder, in combination with lithium or sodium valproate.
Change to listing (Minor submission)	Quetiapine fumarate, tablets, 25 mg, 100 mg, 200 mg and 300 mg (base), Seroquel®, AstraZeneca Pty Ltd	Bipolar disorder	Extend the current Authority Required (STREAMLINED) listing to include maintenance treatment of bipolar 1 disorder, as monotherapy.
Change to listing (Minor submission)	Quetiapine fumarate, tablets (modified release), 50 mg, 200 mg, 300 mg and 400 mg (base), Seroquel XR®, AstraZeneca Pty Ltd.	Bipolar disorder	Request the "bipolar" PBS listings for immediate release quetiapine, be applied to the modified release quetiapine tablets.
Change to listing (Minor submission)	Risperidone, powder for IM injection, 25 mg, 37.5 mg and 50 mg (modified release) with 2 mL diluent in prefilled syringe, Risperdal Consta®, Janssen-Cilag Pty Ltd.	Schizophrenia	Request to remove the NOTE stating no applications for increased maximum quantities and/or repeats will be authorised.
New drug application (Major submission)	Rizatriptan benzoate, tablets, 5 mg and 10 mg (base), wafers, 5 mg and 10 mg (base), Maxalt®, Merck Sharp & Dohme (Australia) Pty Ltd.	Migraine	Authority Required (STREAMLINED) listing for treatment of a patient with a migraine attack.
New drug application (Major submission)	Tenofovir disoproxil fumarate with emtricitabine and efavirenz, tablet 300 mg–200mg–600 mg, Atripla®, Gilead Sciences Pty Ltd.	Human Immunodeficiency Virus (HIV) infection	Section 100 (Highly Specialised Drugs Program) listing for treatment of HIV infection in patients with: (a) CD4 cell counts of less than 500 per cubic millimetre; or (b) Viral load of greater than 10,000 copies per mL.
Change to listing (Major submission)	Tocilizumab, solution for IV infusion, 80 mg in 4 mL, 200 mg in 10 mL and 400 mg in 20 mL, Actemra®, Roche Products Pty Ltd.	Rheumatoid arthritis	Extend the Section 100 (Highly Specialised Drugs Program) listing recommended by PBAC at the July 2009 meeting to include initial and continuing treatment with tocilizumab as monotherapy, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis of

			adults who meet certain criteria.
New drug application (Minor submission)	Triglycerides, long chain with glucose polymer, oral liquid, 250 mL and 1000 mL, ProZero®, Vitaflo Australia Pty Ltd.	Medicinal food	Restricted Benefit listing for: (1) patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae; (2) children with chronic renal disease who are unable to meet their energy requirements with food and formulae where a low protein and a low phosphorus diet (+/- potassium restriction) is required.
New drug application (Minor submission)	Triglycerides, medium chain, emulsion 250 mL, Liquigen®, Nutricia Australia Pty Ltd.	Medicinal food	Restricted Benefit listing for chylous ascites, chylothorax, fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders, intractable epilepsy requiring a ketogenic diet, fatty acid oxidation disorders and hyperlipoproteinaemia Type 1.
New drug application (Major submission)	Ustekinumab (rmc), solution for injection, 45 mg in 0.5 mL, Stelara®, Janssen-Cilag Pty Ltd.	Chronic plaque psoriasis	Authority Required listing for initial and continuing treatment by a dermatologist for adults 18 years of age and over who have severe chronic plaque psoriasis who meet certain criteria.
Change to listing (Major submission)	Varenicline, tablet, 1 mg (as tartrate), Champix®, Pfizer Australia Pty Ltd.	Smoking cessation	To request the addition of a second continuing treatment restriction to the current authority required listing to allow a further 12 weeks of treatment for responders.
New drug application (Minor submission)	Vitamins, minerals and trace elements with carbohydrate, powder 200 g, Paediatric Seravit®, Nutricia Australia Pty Ltd.	Medicinal food	Restricted Benefit listing for children where vitamin and mineral intake is insufficient due to restrictive therapeutic diets for the management of inborn errors of metabolism, multiple food allergies and gastrointestinal disorders.
Change to listing (Major submission)	Zoledronic acid, solution for I.V. infusion, 5 mg (as monohydrate) in 100 mL, Aclasta®, Novartis Pharmaceuticals Australia Pty Ltd.	Paget's disease	Extend the current Authority Required listing to include symptomatic Paget's disease of bone. The submission also requests a Streamlined Authority listing.

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Change to listing (Major submission)	Zoledronic acid, solution for I.V. infusion, 5 mg (as monohydrate) in 100 mL, Aclasta®, Novartis Pharmaceuticals Australia Pty Ltd.	Osteoporosis	Extend the current Authority Required listing to include treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less. The submission also requests a Streamlined Authority listing.
Change to listing (Minor submission)	Zoledronic acid, solution for I.V. infusion, 5 mg (as monohydrate) in 100 mL, Aclasta®, Novartis Pharmaceuticals Australia Pty Ltd.	Osteoporosis	Extend the current primary and secondary prevention osteoporosis listing to include male patients.