

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2010 PBAC MEETING**

Closing date for consumer comments 10 February 2010

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 <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>
Change to listing (Major submission)	Adalimumab, injection, 20 mg in 0.4 mL, 40 mg in 0.8 mL, pre-filled syringe, pre-filled pen, Humira [®] Abbott Australasia Pty Ltd	Juvenile arthritis	Section 100 (Highly Specialised Drugs Program) listing for treatment of patients under 18 years who have severe polyarticular course juvenile chronic arthritis who meet certain criteria.
New drug application (Minor submission)	Adrenaline, I.M. injection, 300 microgram in 0.3 mL single dose syringe auto-injector, Anapen [®] , 150 microgram in 0.3 mL single dose syringe auto-injector, Anapen Junior [®] Link Medical Products Pty Ltd	Severe, allergic reactions	List two strengths of a new form of adrenaline auto-injector.
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, 20 g sachets, MMA/PA Express [®] Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for methylmalonic acidemia and propionic acidemia.
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, 20 g sachets, MMA/PA Gel [®] Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for methylmalonic acidemia and propionic acidemia.
New drug application (Minor submission)	Amino acids – synthetic, formula, powder, 400 g, Neocate Nutra [®] Nutricia Australia Pty Ltd	Medicinal food	Restricted benefit listing for combined intolerance (not infant colic) to cow's milk protein, soy protein and protein hydrolysate formulas.

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Re-submission (Minor submission)	Aprepitant, pack containing 1 capsule 125 mg and 2 capsules 80 mg, Emend® Merck Sharp & Dohme (Australia) Pty Ltd	Anti-emetic, anti-nauseant	Re-submission to extend the current listing to include management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy where the patient has had a prior episode of chemotherapy induced nausea or vomiting (i.e. secondary prophylaxis).
Re-submission (Major submission)	Bortezomib, powder for injection, 1 mg, Velcade® Janssen-Cilag Pty Ltd	Treat multiple myeloma in patients ineligible for transplant	Authority required listing for treatment of a patient with newly diagnosed symptomatic multiple myeloma in combination with a corticosteroid and melphalan or cyclophosphamide who is ineligible for high dose chemotherapy.
Re-submission (Minor submission)	Botulinum toxin type A purified neurotoxin complex, lyophilised powder for IM injection 100 units, Botox® Allergan Australia Pty Ltd	Excessive sweating	Re-submission to extend the current Section 100 (Botulinum Toxin Program) listing to include treatment of 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.
Change to listing (Minor submission)	Brimonidine tartrate with timolol maleate, eye drops, 2 mg - 5 mg (base) per mL (0.2%-0.5%), 5 mL, Combigan® Allergan Australia Pty Ltd	Glaucoma	Change to the restriction wording.
New drug application (Major submission)	Brinzolamide with timolol maleate, eye drops, 10 mg-5 mg (base) per mL, (1%-0.5%), Azarga® Alcon Australia Laboratories (Australia) Pty Ltd	Glaucoma	Restricted benefit listing for reduction of elevated intra-ocular pressure in patients with either open-angle glaucoma or ocular hypertension who are not adequately controlled with timolol 5 mg/mL eye drops.
Re-submission (Major submission)	Capecitabine, tablet, 150 mg, 500 mg, Xeloda® Roche Products Pty Ltd	Cancer treatment	Authority required listing to treat, in combination with a cisplatin-based regimen, of a patient with previously untreated advanced oesophago-gastric cancer with a WHO status of 2 or less.
New drug application (Major submission)	Certolizumab pegol, injection, 200 mg in 1 mL single use pre-filled syringe, Cimzia® UCB Australia Pty Ltd	Monoclonal antibody for use in rheumatoid arthritis and other chronic inflammatory diseases	Authority required listing for the treatment of adult patients with severe active rheumatoid arthritis who meet certain criteria.

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Change to listing (Major submission)	Cetuximab, solution for IV infusion, 2 mg/mL, 50 mL, 5 mg/mL, 20 mL, 5 mg/mL, 100 mL, Erbitux® Merck Serono Australia Pty Ltd	Cancer treatment	Authority required listing for the first line treatment, in combination with chemotherapy regimens, of patients with previously untreated KRAS wild type metastatic colorectal cancer.
New drug application (Major submission)	Eletriptan hydrobromide, tablet, 40 mg (base), 80 mg (base), Relpax® Pfizer Australia Pty Ltd	Treat migraine attack	Authority required listing for the treatment of migraine attacks in patients who meet certain criteria.
Change to listing (Minor submission)	Esomeprazole magnesium trihydrate, tablet, 20 mg, 40 mg, Nexium® AstraZeneca Pty Ltd	Acid related disorders, such as gastro-oesophageal reflux	Increase the number of repeats for the 40 mg tablet, extend the restricted benefit listings of both the 20 mg and 40 mg strengths to include healing and maintenance of gastro-oesophageal reflux disease, scleroderma oesophagus and Zollinger-Ellison syndrome.
Change to listing (Minor submission)	Fentanyl citrate, lozenge, 200 micrograms, 400 micrograms, 600 micrograms, 800 micrograms, 1200 micrograms, 1600 micrograms, Actiq® Orphan Australia Pty Ltd	Cancer pain	Authority required listing for breakthrough pain in patients with advanced metastatic cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.
Re-submission (Minor 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	Re-submission for Section 100 (IVF GIFT Program) listing for prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.
New drug application (Major submission)	Golimumab, injection 50 mg in 0.5 mL, pre-filled syringe, single use pre-filled pen, Simponi® Schering-Plough Pty Ltd	Monoclonal antibody for use in ankylosing spondylitis and other chronic inflammatory diseases	Authority required listing for the treatment of adult patients with active ankylosing spondylitis who meet certain criteria.
New drug application (Major submission)	Golimumab, injection 50 mg in 0.5 mL, pre-filled syringe, single use pre-filled pen, Simponi® Schering-Plough Pty Ltd	Monoclonal antibody for use in rheumatoid arthritis and other chronic inflammatory diseases	Authority required listing for the treatment of adult patients with severe active rheumatoid arthritis who meet certain criteria.

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New drug application (Major submission)	Golimumab, injection 50 mg in 0.5 mL, pre-filled syringe, single use pre-filled pen, Simponi® Schering-Plough Pty Ltd	Monoclonal antibody for use in psoriatic arthritis and other chronic inflammatory diseases	Authority required listing for the treatment of adult patients with severe active psoriatic arthritis who meet certain criteria.
New drug application (Minor submission)	High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate, powder 300 g, KetoCal® Nutricia Australia Pty Ltd	Medicinal food	List an unflavoured version of the current product.
Re-submission (Major submission)	Infliximab, powder for IV infusion, 100 mg, Remicade® Schering-Plough Pty Ltd	Monoclonal antibody for use in Crohn disease and other chronic inflammatory disease	Section 100 (Highly Specialised Drugs Program) listing for the treatment of fistulising Crohn disease in patients who meet certain criteria.
New drug application (Minor submission)	Macrogol 3350, powder for solution, 510 g, OsmoLax® Key Pharmaceuticals Pty Ltd	Constipation	List a new form of macrogol 3350 laxative in the General and Palliative Care Schedules.
Change to listing (Minor submission)	Meloxicam, tablet, 7.5 mg, 15 mg, Meloxibell®, Meloxicam-GA® Generic Health Pty Ltd, Genepharm Pty Ltd	Anti-inflammatory	Add a 'NOTE' to the listing stating bioequivalence between the tablets and capsules.
New drug application (Minor submission)	Methylphenidate hydrochloride, capsule (modified release), 10 mg, Ritalin LA® Novartis Pharmaceuticals Australia Pty Ltd	Attention deficit hyperactivity disorder (ADHD)	List a new strength.
Change to listing (Minor submission)	Milk powder –synthetic, low calcium compound powder 400 g, Locasol® Nutricia Australia Pty Ltd	Medicinal food	Approval sought for minor change to the existing formulation.
Change to listing (Minor submission)	Milk protein with fat formula with vitamins and minerals – carbohydrate free, powder 225 g, Carbohydrate Free Mixture® Nutricia Australia Pty Ltd	Medicinal food	Approval sought for minor change to the existing formulation.

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Re-submission (Major submission)	Nicotine transdermal patch releasing 15 mg per 16 hours, Nicorette [®] Patch Cancer Council Australia, Heart Foundation, Australian Council on Smoking and Health, Quit Victoria	Help stop smoking	Re-submission for an Authority required listing for the treatment of nicotine dependence in concessional patients or patients for whom other smoking cessation pharmacotherapies should not be prescribed because of contraindications, precautions or adverse reactions.
New drug application (Minor submission)	Olanzapine (as benzoate), tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg Olanzapine Generichealth [®] Generic Health Pty Ltd	Schizophrenia, bi-polar disorder	List a benzoate salt of olanzapine as a new generic form (interchangeable).
New drug application (Major submission)	Palonosetron hydrochloride, solution for injection vial, 250 micrograms in 5 mL, Onicit [®] Specialised Therapeutics Australia Pty Ltd	Prevent or treat nausea and vomiting following cancer chemotherapy	Restricted benefit listing for management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.
Re-submission (Minor submission)	Pemetrexed disodium, powder for I.V. infusion, 100 mg (base), 500 mg (base), Alimta [®] Eli Lilly Australia Pty Ltd	Cancer treatment	Re-submission to address cost effectiveness uncertainties in the November 2009 submission for the first-line treatment of non-small cell lung cancer.
New drug application (Major submission)	Perindopril arginine with amlodipine besylate, tablet, 5 mg-5 mg, 5 mg-10 mg, 10 mg-5 mg, 10 mg-10 mg, Coveram [®] Servier Laboratories (Australia) Pty Ltd	Hypertension	Restricted benefit as substitution therapy in patients who are stabilised on treatment with perindopril and amlodipine, given concurrently at the same dose level.
Change to listing (Minor submission)	Posaconazole, oral suspension, 40 mg per mL, 105 mL, Noxafil [®] Schering-Plough Pty Ltd	Anti-infective	Transfer to the Section 100 (Highly Specialised Drugs Program) Schedule from the General Schedule.
New drug listing (Minor submission)	Pramipexole hydrochloride, tablet, 375 microgram, 750 microgram, 1.5 mg, 3 mg, 4.5 mg, Sifrol ER [®] Boehringer Ingelheim Pty Ltd	Parkinson disease	List an extended release formulation.

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Change to listing (Major submission)	Raltegravir potassium, tablet 400 mg (base), Isentress [®] Merck Sharp & Dohme (Australia) Pty Ltd	HIV treatment	Section 100 (Highly Specialised Drugs Program) listing as first-line therapy for patients with HIV infection who meet certain criteria.
New drug application (Minor submission)	Ritonavir, tablet, 100 mg, Norvir [®] Abbott Australasia Pty Ltd	HIV infection	List a tablet form to replace the currently listed capsules.
Change to listing (Major submission)	Rituximab, solution for IV infusion, 100 mg in 10 mL, 500 mg in 50 mL, Mabthera [®] Roche Products Pty Ltd	Monoclonal antibody for use in leukaemia	Authority required listing under Section 85 and a Section 100 listing under the Chemotherapy Pharmaceutical Access Program (CPAP) for the treatment of CD20 positive, chronic lymphocytic leukaemia, in combination with chemotherapy.
Re-submission (Major submission)	Romiplostim, powder for injection, 165 micrograms, 375 micrograms, 625 micrograms, (Nplate [®]) Amgen Australia Pty Ltd	Increases platelet production	Section 100 (Highly Specialised Drugs Program) listing for the initial and continuing treatment of adult patients with chronic immune idiopathic thrombocytopenic purpura who meet certain criteria.
Change to listing (Minor submission)	Rosuvastatin calcium, tablet, 5 mg (rosuvastatin), 10 mg (rosuvastatin), 20 mg (rosuvastatin), 40 mg (rosuvastatin), Crestor [®] AstraZeneca Pty Ltd	Lowers blood cholesterol	Inclusion in the 12 month repeat prescription measure.
New drug application (Major submission)	Salbutamol sulfate, oral pressurised inhalation, 100 micrograms (base) per dose (200 doses), CFC-free formulation with spacer, VentSpacer [®] Medical Developments International Ltd	Relieve asthma symptoms	Restricted benefit for patients who are unable to achieve coordinated use of other metered dose inhalers containing salbutamol or at risk of an acute asthma episode.
New drug application (Major submission)	Saxagliptin, tablets, 2.5 mg, 5 mg, Onglyza [®] Bristol-Myers Squibb Pharmaceuticals	Lowers blood sugars	Authority required (Streamlined) listing for use in type 2 diabetes in combination with metformin or a sulphonylurea.
New drug application (Minor submission)	Tipranavir, oral solution, 100 mg per mL, Aptivus [®] Boehringer Ingelheim Pty Ltd	HIV infection	List a new dosage form.

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Re-submission (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	Monoclonal antibody for use in rheumatoid arthritis and other chronic inflammatory diseases	Section 100 (Highly Specialised Drugs Program) listing for first-line treatment in combination with methotrexate in patients with severe active rheumatoid arthritis who meet certain criteria.
Change to listing (Minor submission)	Triglycerides – medium chain and long chain with glucose polymer, sachets, 16 g, MCT Pro-Cal® Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose, sachet, 100 g, RenaStart® Vitaflo Australia Pty Ltd	Medicinal foods	Change maximum quantity.
New drug application (Minor submission)	Valganciclovir hydrochloride, powder for oral solution, 50 mg per mL, Valcyte® Roche Products Pty Ltd	Anti-viral	Section 100 (Highly Specialised Drugs Program) listing of a new dosage form with the same restrictions as the 450 mg tablets.
New drug application (Major submission)	Vildagliptin, tablet, 50 mg, Galvus® Novartis Pharmaceuticals Australia Pty Ltd	Lowers blood sugars	Authority required (Streamlined) listing for use in type 2 diabetes in combination with metformin or a sulphonylurea.