

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

**Closing date for consumer comments 9 June 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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<b>Submission type</b> <i>(new drug application, changes to listings, resubmissions)</i>	<b>Drug Name, form(s), strength(s) and Sponsor</b> <i>(Drug name, form, strength, Trade name<sup>®</sup>, Sponsor)</i>	<b>Drug Type and Use</b> <i>(What is the drug used to treat?)</i>	<b>Listing requested by Sponsor / Purpose of Submission</b> <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 (Minor submission)	Alendronate sodium, tablet equivalent to 70 mg alendronic acid, Fosamax Once Weekly <sup>®</sup>  Alendronate sodium with colecalciferol, tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol, Fosamax Plus <sup>®</sup> , Alendronate sodium with colecalciferol, tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol, Fosamax Plus 70 mg/140 mcg <sup>®</sup> , Alendronate sodium with colecalciferol and calcium, pack containing 4 tablets equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol and 48 tablets calcium carbonate 1.5 g (equivalent to 500 mg elemental calcium), Fosamax Plus D-Cal <sup>®</sup> , Merck Sharp & Dohme (Australia) Pty Ltd	Osteoporosis	Extend the current listing to include the treatment of corticosteroid-induced osteoporosis in a patient who meets certain criteria.
New drug application (Major submission)	Aliskiren, tablets, 150 mg and 300 mg (as hemifumarate), Rasilez <sup>®</sup> , Novartis Pharmaceuticals Australia Pty Ltd	Antihypertensive	Unrestricted Benefit listing for the treatment of hypertension.
Change to listing (Minor submission)	Amino acid formula with vitamins and minerals without lysine and low in tryptophan, powder 500 g, XLYS, LOW TRY Maxamaid <sup>®</sup> , Nutricia Australia Pty Ltd	Medicinal food	Request a change to the age restriction from a child less than 7 years to a child less than 9 years in the current restricted benefit listing for proven glutaric aciduria type1.
New drug application (Minor submission)	Amino acid synthetic formula with supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides, compounded powder, 400 g, Neocate LCP plus MCT <sup>®</sup> , Nutricia Australia Pty Ltd	Medicinal food	Authority Required listing for treatment of combined intolerance (not infant colic) to cow's milk protein, soy protein and protein hydrolysate formulas in a child from birth to 1 year of age, where the child has been assessed by a suitably qualified allergist or paediatrician.
New drug application (Major submission)	Amlodipine (as besylate) with valsartan and hydrochlorothiazide, tablets, 5 mg-160 mg-12.5 mg, 5 mg-160 mg-25 mg, 10 mg-160 mg-12.5 mg, 10 mg-160 mg-25 mg and 10 mg-320 mg-25 mg, Exforge HCT <sup>®</sup> Novartis Pharmaceuticals Australia Pty Ltd	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in patients who are already adequately controlled on the triple combination of amlodipine, valsartan and hydrochlorothiazide (as individual or combination therapies).
New drug application	Amlodipine with valsartan, tablets, 5 mg (as besylate)-320 mg, 10 mg (as besylate)-320 mg, Exforge5/320 <sup>®</sup> , Exforge	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in a patient who is not adequately controlled with either of the

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(Minor application)	10/320 <sup>®</sup> , Novartis Pharmaceuticals Australia Pty Ltd		drugs in the combination.
New drug application (Minor application)	Artemether with lumefantrine, tablet 20 mg-120 mg (dispersible), Riamet <sup>®</sup> , Novartis Pharmaceuticals Australia Pty Ltd	Anti-malarial	Authority Required listing of a new dispersible formulation under the current listing conditions for the treatment of suspected or confirmed malaria due to Plasmodium falciparum.
New drug application (Minor application)	Brimonidine tartrate, eye drops 1.5 mg per mL (0.15%), 5 mL, Alphagan <sup>®</sup> P 1.5, Allergan Australia Pty Ltd	Glaucoma	1. Unrestricted benefit listing of a new form and strength of brimonidine eye drops for lowering elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension.  2. Same listing requested on the Optometrical Schedule.
Re-submission (Minor application)	Cetrorelix, powder for injection with diluent syringe, 250 microgram (as acetate), Cetrotide <sup>®</sup> , Merck Serono Australia 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 (ART).
Change to listing (Minor application)	Cetuximab, solution for IV infusion, 100 mg in 20 mL, 100 mg in 50 mL, 500 mg in 100 mL, Erbitux <sup>®</sup> , Merck Serono Australia Pty Ltd	Anti-cancer drug	Extend the current Authority Required listing to include initial and continuing treatment as monotherapy or in combination with chemotherapy following failure of chemotherapy in K-Ras wild type patients with metastatic colorectal cancer.
Re-submission (Major submission)	Cilostazol, tablets 50 mg and 100 mg, Pletal <sup>®</sup> , PharmaLink Pty Ltd	Intermittent claudication	Authority Required listing for the treatment of symptomatic improvement of intermittent claudication as indicated by increased maximal and pain-free walking distances, in patients who do not have rest pain and who do not have evidence of peripheral tissue necrosis.
New drug application (Major submission)	Darunavir, tablet, 400 mg (as ethanolate), Prezista <sup>®</sup> , Janssen-Cilag Pty Ltd	HIV-infection	S100 (Highly Specialised Drugs Program) listing for treatment in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily, of HIV infection in a protease inhibitor naïve patient 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.
New drug application (Major submission)	Degarelix, powder for subcutaneous injections (modified release), 80 mg and 120 mg, (as acetate) with solvent, syringe and needles, Firmagon <sup>®</sup> , Ferring Pharmaceuticals Pty Ltd	Anti-cancer drug	Authority Required listing for the treatment of locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.
New drug application (Major submission)	Denosumab, injection, 60 mg in 1 mL, single use pre-filled syringe, Prolia <sup>®</sup> , Amgen Australia Pty Ltd	Osteoporosis	Authority Required (STREAMLINED) listing for: 1. the treatment of osteoporosis in women aged 70 years of age or older with a BMD T score of -3.0 or less, and

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			2. the treatment of established post-menopausal osteoporosis in patients with fracture due to minimal trauma.
New drug application (Minor submission)	Epoetin lambda, injection, 1000 units in 0.5 mL, 2000 units in 1.0 mL, 3000 units in 0.3 mL, 4000 units in 0.4 mL, 5000 units in 0.5 mL, 6000 units in 0.6 mL, 8000 units in 0.8 mL and 10,000 units in 1.0 mL, pre-filled syringes, Novicrit <sup>®</sup> , Novartis Pharmaceuticals Australia Pty Ltd	Anaemia	S100 (Highly Specialised Drugs Program) listing for the treatment of anaemia requiring transfusion, where Hb level of less than 100 g per L and intrinsic renal disease is the primary cause of anaemia as assessed by a nephrologist.
Change to listing (Minor submission)	Esomeprazole magnesium trihydrate, tablet (enteric coated), equivalent to 40 mg esomeprazole, Nexium <sup>®</sup> , AstraZeneca Pty Ltd	Proton-pump inhibitor	Request to remove the reference to increased repeats from the existing NOTE to allow authorisation of increased repeats but not maximum quantities.
Re-submission (Major submission)	Everolimus, tablets, 5 mg and 10 mg, Afinitor <sup>®</sup> , Novartis Pharmaceuticals Australia Pty Ltd.	Anti-cancer drug	Authority Required listing for the initial and continuing treatment of Stage IV clear cell variant renal cell carcinoma in a patient with a WHO status of 2 or less who meets certain criteria.
Change to listing (Minor submission)	Exenatide, pre-filled injection pen, 5 micrograms per dose, 10 micrograms per dose, Byetta <sup>®</sup> , Eli Lilly Australia Pty Ltd	Diabetes	Request the PBAC allow patients to switch between agents in three classes namely gliptins, glitazones and glucagon-like peptides without having to requalify with respect to glycosylated haemoglobin levels (HbA1c) be applied to the listing of exenatide.
Change to listing (Minor submission)	Hydromorphone hydrochloride, tablets, 4 mg, 8 mg, 16 mg, 32 mg and 64 mg (modified release), Jornista <sup>®</sup> , Janssen-Cilag Pty Ltd	Pain relief	To seek a change to the current pack size from 10 to 14, for all five strengths of hydromorphone hydrochloride tablets.
New drug application (Major submission)	Icatibant, injection, 30 mg in 3 mL, single use pre-filled syringe, (as acetate), Firazyr <sup>®</sup> , Shire Australia Pty Limited	Acute hereditary angioedema	Authority Required listing for anticipated emergency treatment, initiated by a specialist immunologist or other relevant specialist, of laryngeal/oro-pharyngeal and severe abdominal attacks of acute hereditary angioedema in patients with confirmed diagnosis of C1-esterase inhibitor deficiency.
Re-submission (Major submission)	Imatinib, tablets, 100 mg and 400 mg, (as mesylate), Glivec <sup>®</sup> , Novartis Pharmaceuticals Australia Pty Ltd.	Anti-cancer drug	Authority Required listing for the adjuvant treatment of an adult 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.
New drug application (Major submission)	Losartan, tablets, 25 mg and 50 mg (as potassium), Cozavan <sup>®</sup> , Alphapharm Pty Limited	Antihypertensive	Unrestricted Benefit listing for the treatment of hypertension.
New drug application (Minor submission)	Mesalazine, suppositories (moulded), 1 g, 28, Salofalk <sup>®</sup> , Orphan Australia Ltd Pty	Anti-inflammatory for bowel disease.	Restricted benefit listing for acute episodes of mild to moderate ulcerative proctitis.

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Change to listing (Major submission)	Miglustat, capsule, 100 mg, Zavesca <sup>®</sup> , Actelion Pharmaceuticals Australia Pty Ltd	Niemann-Pick type C disease	Request for inclusion on the Life Saving Drugs Program (LSDP) for the treatment of progressive neurological manifestations in adults and paediatric patients with Niemann-Pick type C disease.
New drug application (Major submission)	Olmesartan medoxomil with amlodipine (as besylate), tablets, 20 mg-5 mg, 20 mg-10 mg, 40 mg-5 mg and 40 mg-10 mg, Sevikar <sup>®</sup> , Schering-Plough Pty Ltd	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in patients who are not adequately controlled with either angiotensin II receptor antagonist or dihydropyridine calcium channel blocker monotherapy.
New drug application (Major submission)	Oxycodone hydrochloride and naloxone hydrochloride dihydrate, tablets, 5 mg-2.5 mg, 10 mg-5 mg, 20 mg-10 mg and 40 mg-20 mg (controlled release), Targin <sup>®</sup> , Mundipharma Pty Ltd	Pain relief	Restricted Benefit listing for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.
New drug application (Major submission)	Pazopanib, tablets, 200 mg and 400 mg (as hydrochloride), Votrient <sup>®</sup> , GlaxoSmithKline Australia Pty Ltd	Anti-cancer drug	Authority Required listing for the initial and continuing treatment of Stage IV clear cell variant renal cell carcinoma in an adult patient who meets certain criteria.
New vaccine application (Major submission)	Pneumococcal polysaccharide conjugate vaccine, 13 valent adsorbed, injection, 0.5 mL, pre-filled syringe, Prevenar-13 <sup>®</sup> , Wyeth Australia Pty Limited	Pneumococcal disease.	Request listing on the National Immunisation Program as a replacement for Prevenar for vaccination against pneumococcal disease in infants.
New drug application (Minor submission)	Psyllium hydrophilic mucilloid, oral powder (orange-flavoured, sugar-free), 283 g and 425 g, Metamucil Orange Smooth <sup>®</sup> , Psyllium hydrophilic mucilloid, oral powder, (non-flavoured), 336 g and 504 g, Metamucil Natural Regular <sup>®</sup> , Procter & Gamble Australia Pty Ltd	Laxative.	Restricted Benefit listing for the following: Hypercholesterolemic patients who suffer from chronic constipation. Patients who suffer from chronic constipation but experience adverse effects with chemical laxatives. Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies. Patients who are receiving long term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities. Patients receiving palliative care. Constipation in patients with malignant neoplasia. Anorectal congenital abnormalities. Megacolon.
Re-submission (Major submission)	Quetiapine fumarate, tablets, 25 mg, 100 mg, 200 mg and 300 mg (base), Seroquel <sup>®</sup> ; tablets (modified release), 50 mg, 200 mg, 300 mg and 400 mg, Seroquel XR <sup>®</sup> , AstraZeneca Pty Ltd	Bipolar disorder	Extend the current Authority Required (STREAMLINED) listing to include monotherapy treatment of bipolar disorder with the addition of a mood stabiliser (lithium or sodium valproate) as clinically appropriate, OR change the current PBS listing to the treatment of bipolar disorder.
Re-submission	Ribavirin and Peginterferon alfa-2a, packs containing 112	Hepatitis C	Extend the current S100 (Highly Specialised Drugs Program)

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(Major submission)	tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms, 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms, 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms, 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms, Pegasys RBV <sup>®</sup> , Roche Products Pty Ltd		listing to include the treatment of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa who meet certain criteria.
Re-submission (Major submission)	Risedronate sodium, tablets, 5 mg and 30 mg, Actonel <sup>®</sup> , 35 mg, Actonel Once-a Week <sup>®</sup> , 150 mg, Once-a-Month <sup>®</sup> ; 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 <sup>®</sup> ; Risedronate sodium and calcium carbonate with colecalciferol, pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, Actonel Combi D <sup>®</sup> , Sanofi-Aventis Australia Pty Ltd	Osteoporosis	Request the PBAC to re-consider its recommendation that risedronate sodium and its combination formulations are interchangeable with alendronate and its combination formulations on an individual patient basis in the treatment of osteoporosis as well as in the treatment of Paget disease.
Re-submission (Minor submission)	Risedronate sodium, tablets, 5 mg and 30 mg, Actonel <sup>®</sup> , 35 mg, Actonel Once-a Week <sup>®</sup> , 150 mg, Once-a-Month <sup>®</sup> ; 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 <sup>®</sup> ; Risedronate sodium and calcium carbonate with colecalciferol, pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, Actonel Combi D <sup>®</sup> , Sanofi-Aventis Australia Pty Ltd	Osteoporosis	To provide evidence of an increased risk of serious atrial fibrillation events with alendronate, used to support the request that the PBAC re-consider its recommendation that risedronate and alendronate are interchangeable on an individual patient basis.
Re-submission (Minor submission)	Romiplostim, powder for injection, 100 micrograms, 250 micrograms and 500 micrograms, Nplate <sup>®</sup> , Amgen Australia Pty Ltd	Idiopathic thrombocytopenia purpura (ITP)	Assess the cost-effectiveness as the volume in the vial has changed.
Change to listing (Major submission)	Rosuvastatin, tablet, 20 mg (as calcium), Crestor <sup>®</sup> , AstraZeneca Pty Ltd	Lipid lowering	Extend the current Restricted Benefit listing to include the primary prevention of cardiovascular events in individuals (men aged 50 years and over or women aged 60 years and over) with a LDL-C < 3.4 mmol/L and C-reactive protein (CRP) level > 2 mg/L who have no established cardiovascular disease,

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			diabetes, chronic inflammatory conditions nor active infection.
Re-submission (Minor submission)	Sevelamer hydrochloride, tablet, 800 mg, Renagel <sup>®</sup> , Genzyme Australasia Pty Ltd	Binds phosphate in patients with end stage kidney disease.	Request a change of listing category from Authority Required to Authority Required (STREAMLINED).
Re-submission (Major submission)	Solifenacin, tablets, 5 mg and 10 mg, (as succinate), Vesicare <sup>®</sup> , Orphan Australia Pty Ltd	Overactive bladder and symptoms of urge urinary incontinence	Restricted Benefit listing for the treatment of detrusor overactivity in a patient who cannot tolerate oral oxybutynin.
New drug application (Minor submission)	Tacrolimus, capsules, 0.5 mg, 1 mg and 5 mg (prolonged release), Prograf XL <sup>®</sup> , Janssen-Cilag Pty Ltd	Immunosuppressant	Request listing of a new prolonged release formulation of tacrolimus under the current listing conditions (organ and tissue transplantation).
New drug application (Major submission)	Topotecan, capsules, 0.25 mg and 1 mg (as hydrochloride), Hycamtin <sup>®</sup> , GlaxoSmithKline Australia Pty Ltd	Anti-cancer drug	Authority Required (STREAMLINED) listing for the treatment of relapsed small cell lung cancer where intravenous therapy is inappropriate.