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

**Closing date for consumer comments 10 June 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.

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

**Closing date for consumer comments 10 June 2009**

| **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)* |
|---|---|---|---|
| New drug application<br><br>(Major submission) | Ambrisentan, tablets, 5 mg, 10 mg, Volibris®, GlaxoSmithKline Australia Pty Ltd | Pulmonary arterial hypertension | Section 100 listing for the treatment of primary pulmonary arterial hypertension and pulmonary arterial hypertension associated with connective tissue disease in patients with WHO functional class III or IV symptoms. |
| New drug application<br><br>(Minor submission) | Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, oral liquid, 125 mL, MSUD Anamix Junior LQ®, Nutricia Australia Pty Ltd | Medicinal food | Restricted benefit listing for maple syrup urine disease. |
| New drug application<br><br>(Minor submission) | Arachidonic acid with docosahexanoic acid, Sachets 4g, containing 200 mg arachidonic acid and 100 mg docosahexanoic acid, KeyOmega®, Vitaflo Australia Pty Ltd | Medicinal food | Restricted benefit listing for use in inborn errors of metabolism. |
| New drug application<br><br>(Minor submission) | Artemether with lumefantrine, tablet, 20 mg – 120 mg, Riamet®, Novartis Pharmaceuticals Australia Pty Ltd | Anti-malarial | Restricted benefit or Authority required listing for the treatment of suspected or confirmed uncomplicated malaria due to *Plasmodium falciparum*. |
| New drug application<br><br>(Major submission) | Azacitidine, powder for injection, 100 mg, Vidaza®, Celgene Pty Ltd | Myelodysplastic syndrome<br>Chronic myelomonocytic leukaemia<br>Acute myeloid leukaemia | Section 100 listing for the treatment of myelodysplastic syndrome or chronic myelomonocytic leukaemia or acute myeloid leukaemia in patients who meet certain criteria. |
| Change to listing<br><br>(Major submission) | Bortezomib, powder for injection, 1 mg, 3.5 mg (solvent required), Velcade®, Janssen-Cilag Pty Ltd | Anti-cancer drug | To extend the current Authority required listing to include use as first line therapy in combination with a corticosteroid and melphalan or cyclophosphamide in the treatment of multiple myeloma in patients who meet certain criteria. |
| Change to listing<br><br>(Minor submission) | Botulinum toxin type A purified neurotoxin complex, , lyophilised powder for I.M. injection, 100 units, Botox®, Allergan Australia, Pty Ltd | Spasticity | Requests extending the S100 listing to include treatment of moderate-severe spasticity of the upper limbs in adults with multiple sclerosis, traumatic brain injury and spinal cord injury |

| | | | |
|---|---|---|---|
| | | | as an adjunct to physical therapy. |
| New drug application<br><br>(Major submission) | Calcipotriol with betamethasone dipropionate, ointment, 50 mcg – 500 mcg per g (0.005% - 0.05%), 30 g, Daivobet®, CSL Biotherapies | Psoriasis | Restricted benefit listing for the treatment of chronic stable plaque type psoriasis |
| Change to listing<br><br>(Major submission) | Capecitabine, tablets, 150 mg, 500 mg, Xeloda®, Roche Products Pty Ltd | Anti-cancer drug | To extend the current Authority required listing to include the treatment of previously untreated advanced oseophago-gastric cancer, in combination with a platinum based regimen. |
| New drug application<br><br>(Minor submission) | Carbohydrate with branched chain amino acids, sachets, 50 g, Hepatamine®, Nutricia Australia Pty Ltd | Medicinal food | Requests a Restricted benefit listing for cirrhosis of the liver, hepatic encephalopathy resistant to drug therapy, patients awaiting liver transplantation, and patient undergoing curative resection for hepatocellular carcinoma. |
| Change to listing<br><br>(Minor submission) | Carbohydrate, fat, vitamins, minerals and trace elements, powder, 400 g, Energivit®, Nutricia Australia Pty Ltd | Medicinal food | To notify of minor changes to the current formulation. |
| Re-submission<br><br>(Minor submission) | Cetuximab, solution for I.V. infusion 100 mg in 20 mL, 100 mg in 50 mL, and 500 mg in 100 mL, Erbitux®, Merck Serono Australia Pty Ltd | Anti-cancer drug | Re-submission for an Authority required listing for third-line treatment of patients with K-Ras wild type metastatic colorectal cancer in combination with irinotecan. |
| New drug application<br><br>(Major submission) | Cilostazol, tablets, 50 mg, 100 mg, Pletal®, PharmaLink Pty Ltd | Intermittent claudication (occlusion of a blood vessel causing pain or discomfort) | Authority required listing for the symptomatic improvement of intermittent claudication. |
| Change to listing<br><br>(Major submission) | Cinacalcet hydrochloride, tablets, 30 mg, 60 mg, 90 mg (base), Sensipar®, Amgen Australia Pty Ltd | Hyperparathyroidism (excessive production of parathyroid hormone) Hypercalcaemia (high calcium levels in the blood) | To extend the current Authority required listing to include: (i) treatment of primary hyperparathyroidism for whom parathyroidectomy is not an option; and (ii) persistent or recurrent hypercalcaemia following resection of parathyroid carcinoma. |
| New drug application<br><br>(Major submission) | Dabigatran etexilate mesilate, capsules, 75 mg, 110 mg, Pradaxa®, Boehringer Ingelheim Pty Ltd | Anticoagulant (blood clot prevention) | Authority required listing for the prevention of venous thromboembolic events in adult patients undergoing elective total knee replacement surgery. |

**Closing date for consumer comments 10 June 2009**

| | | | |
|---|---|---|---|
| New drug application<br><br>(Minor submission) | Docosahexanoic acid, Sachets 4g, containing 200 mg docosahexanoic acid, DocOmega®, Vitaflo Australia Pty Ltd | Medicinal food | Restricted benefit listing for use in inborn errors of metabolism. |
| New drug application<br><br>(Major submission) | Dutasteride, capsule, 0.5 mg, Avodart®, GlaxoSmithKline Australia Pty Ltd | Enlarged prostate | Authority required (Streamlined) listing for the treatment of benign prostatic hyperplasia in men over 50 years who meet certain criteria. |
| Re-submission<br><br>(Minor submission) | Ezetimibe with simvastatin, tablets, 10 mg - 10 mg, 10 mg – 20 mg, Vytorin®, Merck Sharp & Dohme (Australia) Pty Ltd, Schering-Plough Pty Ltd | High cholesterol and lipid levels | Authority required (Streamlined) listings of two new strengths for the treatment of homozygous familial hypercholesterolaemia in patients who are eligible for lipid lowering medication in combination with a HMG CoA reductase inhibitor (a “statin”). |
| New drug application<br><br>(Minor submission) | Gliclazide, tablet (modified release), 60 mg, Diamicron MR®, Servier Laboratories (Australia) Pty Ltd | Diabetes Type 2 | Requests listing a new, higher strength. |
| New drug application<br><br>(Major submission) | Hydroxyethyl starch 130/0.4, I.V infusion, 60 g per 1 L, 500 mL, Voluven® 6%, Pharmatel Fresenius Kabi Pty Ltd | Hypovolemia (blood loss) | Unrestricted benefit listing. |
| Change to listing<br><br>(Minor submission) | Imiquimod, cream, 50 mg per g (5%), 250 mg single use sachets, Aldara®, iNova Pharmaceuticals (Australia) Pty Ltd | Skin cancers | Requests and increase in the maximum quantity from 1 to 2 and a decrease in repeats from 1 to nil. Also requests an alteration to the NOTE to allow increased quantities of up to 30 sachets. |
| New drug application<br><br>(Major submission) | Influenza vaccine, suspension for injection, pre-filled syringe, 15 micrograms/strain/0.1 mL (containing A/New Caledonia/20/99, A/Wisconsin/67/2005, B/Malaysia/2506/2004 like strains), Intanza®, Sanofi Pasteur Pty Ltd | Influenza virus | Inclusion on the National Immunisation Program for vaccination against influenza for patients aged 65 years and older via the intradermal route. |
| Re-submission<br><br>(Major submission) | Ivabradine hydrochloride, film coated tablets, 5 mg, 7.5 mg, Coralan®, Servier Laboratories (Australia) Pty Ltd | Angina | Re-submission seeking Authority required (Streamlined) listing for the treatment of chronic stable angina in patients who meet certain criteria. |

**Closing date for consumer comments 10 June 2009**

| | | | |
|---|---|---|---|
| Re-submission<br><br>(Minor submission) | Methylnaltrexone bromide, injection, 12 mg in 0.6 mL (base), Relistor®, Wyeth Australia Pty Ltd | Constipation | Re-submission requesting an Authority required Palliative Care Schedule listing for initial and continuing treatment of opioid-induced constipation in patients who have failed/unable to tolerate laxative therapies. |
| Re-submission<br><br>(Major submission) | Montelukast sodium, chewable tablets, 4 mg (base), 5 mg (base) and film coated tablets, 10 mg, Singulair®, Merck Sharp & Dohme (Australia) Pty Ltd | Asthma | (i) To change the current Authority required (Streamlined) listing to a Restricted benefit listing;<br>(ii) To extend the current listing to include treatment of residual exercise related asthma symptoms despite receiving optimal dose inhaled corticosteroid therapy; and<br>(iii) To request listing a new strength (10 mg). |
| New drug application<br><br>(Major submission) | Olanzapine (pamoate monohydrate), powder for injection with diluent vial, 210 mg, 300 mg, 405 mg, Zyprexa Relprevv®, Eli Lilly Australia Pty Ltd | Schizophrenia | Authority required listing for maintenance treatment of schizophrenia in adult patients sufficiently stabilised during acute treatment with oral olanzapine. |
| Change to listing<br><br>(Minor submission) | Pegfilgrastim, injection, 6 mg in 0.6 mL, single use pre-filled syringe, Neulasta®, Amgen Australia Pty Ltd | Neutropenia (low levels of a type of white blood cells) | Requests extending the current S100 listing to include use as primary prophylaxis of chemotherapy induced neutropenia in patients with inoperable squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx treated with docetaxel, cisplatin and 5-fluorouracil. |
| New drug application<br><br>(Major submission) | Pneumococcal polysaccharide conjugate vaccine, turbid liquid suspension for injection (0.5 mL) in pre-filled syringe or vial, Synflorix®, GlaxoSmithKline Australia Pty Ltd | Vaccination against disease caused by *Streptococcus pneumoniae* | Inclusion on the National Immunisation Program for immunisation of infants and children aged 6 weeks up to 2 years against disease caused by *S.pneumoniae*. |
| New drug application<br><br>(Minor submission) | Polyethylene glycol 400, eye drops, 2.5 mg per mL (0.25 %), 15 mL multi-dose eye drops, Blink® Intensive Tears Protective Eye Drops, 2.5 mg per mL (0.25 %), single dose units 0.4 mL, 20, Blink® Intensive Tears Protective Eye Drops – Unit dose, Advanced Medical Optics Australia Pty Ltd | Dry eyes | Requests Restricted benefit listings in the General and Optometrical schedules for severe dry eye syndrome, including Sjorgren's syndrome. |
| Re-submission<br><br>(Major submission) | Pramipexole hydrochloride, tablets, 125 micrograms, 250 micrograms, 1 mg, Sifrol®, Boehringer Ingelheim Pty Ltd | Parkinson disease | Re-submission to extend the current Restricted benefit listing to include use as monotherapy for idiopathic Parkinson disease in patients with motor disability and no evidence of cognitive impairment. |

**Closing date for consumer comments 10 June 2009**

| | | | |
|---|---|---|---|
| New drug application<br><br>(Major submission) | Prasugrel hydrochloride, tablets, 5 mg, 10 mg (base), Effient®, Eli Lilly Australia Pty Ltd | Antiplatelet drug | Authority required listing for the initial and continuing treatment of acute coronary syndromes (myocardial infarction or unstable angina) in combination with aspirin in patients who are to undergo percutaneous coronary intervention. |
| Change to listing<br><br>(Minor submission) | Ribavirin and peginterferon alfa-2a, various strengths, forms and pack sizes, Pegasys RBV®, Roche Products Pty Ltd | Hepatitis C | Requests extending the current S100 listing to include treatment of patients who have failed one prior attempt at interferon based therapy (non-pegylated or pegylated) who meet certain criteria. |
| New drug application<br><br>(Major submission) | Romiplostim (rbe), powder for injection, 165 mcg, 375 mcg, 625 mcg, Nplate®, Amgen Australia Pty Ltd | Thrombocytopenia (low platelet levels in the blood) | Section 100 listing for the initial and continuing treatment of adult patients with chronic immune (idiopathic) thrombocytopenic purpura who meet certain criteria. |
| Change to listing<br><br>(Minor submission) | Sevelamer hydrochloride, tablet, 800 mg, Renagel®, Genzyme Australasia Pty Ltd | Hyperphosphataemia (high phosphate levels in the blood) | Requests a change to the current Section 85 listing from the current Authority required to an Authority required (Streamlined) listing. |
| Re-submission<br><br>(Major submission) | Sunitinib malate, capsules, 12.5 mg, 25 mg, 50 mg (base), Sutent®, Pfizer Australia Pty Ltd | Anti-cancer drug | Re-submission seeking an Authority required listing for initial and continuing treatment of gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance. |
| Re-submission<br><br>(Major submission) | Tenofovir disoproxil fumarate, tablet, 300 mg, Viread®, Gilead Sciences Pty Ltd | Hepatitis B | Re-submission to extend the November 2008 PBAC recommendation for a Section 100 listing for treatment naïve patients who are hepatitis B antigen positive to include treatment of chronic hepatitis B in treatment naïve hepatitis B antigen negative patients AND patients (hepatitis B antigen negative and positive) who have failed prior anti-hepadnaviral therapy who meet certain criteria. |
| Change to listing<br><br>(Minor submission) | Thyrotropin alfa, powder for injection, 0.9 mg, Thyrogen®, Genzyme Australasia Pty Ltd | Ablation of thyroid remnant tissue | Requests a change from the current Authority required listing to an Authority required (Streamlined) or a Restricted benefit listing. |
| New drug application<br><br>(Minor submission) | Tiotropium bromide monohydrate, cartridge containing solution for inhalation, 2.5 micrograms tiotropium per actuation (for use with inhaler), Spiriva Respimat®, Boehringer Ingelheim Pty Ltd | Chronic obstructive pulmonary disease | Requests a Restricted benefit listing for a new dosage form for the long term maintenance treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease. |

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

**Closing date for consumer comments 10 June 2009**

| | | | |
|---|---|---|---|
| New drug application<br><br>(Major submission) | Tocilizumab, solution for I.V. infusion, 80 mg in 4 mL, 200 mg in 10 mL, 400 mg in 20 mL, Actemra®, Roche Products Pty Ltd | Rheumatoid arthritis | Section 100 listing for the treatment of adult patients with severe active rheumatoid arthritis in combination with methotrexate or a non-biological disease modifying anti-rheumatic drug who meet certain criteria. |
| Change to listing<br><br>(Minor submission) | Triglycerides – medium chain, formula, compound powder, 420 g, Caprilon®, Nutricia Australia Pty Ltd | Medicinal food | To request minor changes to the current formulation. |
| Re-submission<br><br>(Minor submission) | Valsartan with hydrochlorothiazide, tablets, 320 mg -12.5 mg, 320 mg – 25 mg, Co-Diovan®, Novartis Pharmaceuticals Australia Pty Ltd | Anti-hypertensive | Re-submission seeking Restricted benefit listings for treatment of hypertension not adequately controlled with valsartan 320 mg monotherapy and in patients stabilised on concomitant valsartan 320 mg and hydrochlorothiazide 12.5 mg or 25 mg. |
| Change to listing<br><br>(Minor submission) | Voriconazole, tablets, 50 mg, 200 mg, Vfend®, Pfizer Australia Pty Ltd | Anti-infective | Requests an increase in the number of repeats available from nil to five. |

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

**Closing date for consumer comments 10 June 2009**