

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

**Closing date for consumer comments 6 October 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 (Major submission)	Adalimumab, injection, 40 mg in 0.8 mL pre-filled syringe, 40 mg in 0.8 mL pre-filled pen, Humira <sup>®</sup>  Abbott Australasia Pty Ltd	Crohn disease	Authority required listing for the treatment of patients with Crohn disease and who have fistula(s).
New drug application (Major submission)	Adapalene with benzoyl peroxide, gel, 1 mg–25 mg per g (0.1%-2.5%), 30 g, Epiduo Gel <sup>®</sup>  Galderma Australia Pty Ltd	Acne	Restricted benefit listing for: 1) The acute management of severe acne vulgaris as adjunctive therapy to an oral antibiotic; and 2) Maintenance treatment of severe acne vulgaris.
Change to listing (Minor submission)	Adrenaline, injections, 150 micrograms in 0.3 mL and 300 micrograms in 0.3 mL, single dose syringe auto-injector, EpiPen Jr <sup>®</sup> and EpiPen <sup>®</sup>  Alphapharm Pty Ltd	Allergic reactions	Requests a change from an Authority required listing to an Authority required (Streamlined) listing.
New drug application (Major submission)	Agomelatine, tablet, 25 mg, Valdoxan <sup>®</sup>  Servier Laboratories (Australia) Pty Ltd	Anti-depressant	Restricted benefit listing for major depressive disorders.
Re-submission (Major submission)	Alglucosidase alfa, powder for I.V. infusion, 50 mg in 10 mL, Myozyme <sup>®</sup>  Genzyme Australasia Pty Ltd	Pompé disease	Life Saving Drugs Program listing for the treatment of patients with late onset Pompé disease.
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without lysine and low in tryptophan, sachets 25 g, GA Express <sup>®</sup>  Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for a child aged from 3 to 10 years with proven glutaric aciduria type 1.

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New drug application (Minor submission)	Amino acid formula with vitamins and minerals without phenylalanine, gel (ready prepared), 85 g, PKU Squeezie®  Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for phenylketonuria.
New drug application (Minor submission)	Arginine with carbohydrate, sachets 4 g containing 2000 mg arginine, Arginine 2000®  Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing of a higher strength product for urea cycle disorders.
New drug application (Major submission)	Aztreonam, powder for inhalation, 75 mg, with diluent, Cayston®  Gilead Sciences Pty Ltd	Anti-infective for use in cystic fibrosis	Section 100 (Highly Specialised Drugs Program) listing for the control of gram-negative bacteria, particularly <i>P. aeruginosa</i> in the respiratory tract of patients with moderate to severe cystic fibrosis who meet certain criteria.
Change to listing (Major submission)	Bevacizumab, solution for I.V. infusion, 100 mg in 4 mL and 400 mg in 16 mL, Avastin®  Roche Products Pty Ltd	Anti-cancer drug	Authority required and Section 100 (Chemotherapy Pharmaceutical Access Program) listing for the treatment as monotherapy of relapsed or progressing glioblastoma multiforme.
New drug application (Minor submission)	Budesonide with eformoterol fumarate dihydrate, oral pressurised inhalation, 200 mcg – 6 mcg per dose, Symbicort Rapihale®  AstraZeneca Pty Ltd	Asthma and chronic obstructive pulmonary disease (COPD)	Requests listing of a new form of a fixed-dose combination product for the same indications as the currently listed product, Symbicort Turbuhaler 400/12®, and for the extension to listing for the treatment of COPD sought in the major submission to this meeting.
Change to listing (Major submission)	Budesonide with eformoterol fumarate dihydrate, powder for oral inhalation in breath activated devices, 400 microgram- 12 microgram per dose, Symbicort®  AstraZeneca Pty Ltd	Chronic obstructive pulmonary disease (airways obstruction)	Restricted benefit listing for the symptomatic treatment of moderate to severe chronic obstructive pulmonary disease in patients who meet certain criteria.
Change to listing (Minor submission)	Cinacalcet hydrochloride, tablet, 30 mg, 60 mg and 90 mg (base), Sensipar®  Amgen Australia Pty Ltd	Hyperparathyroidism Hypercalcaemia	Requests a change from an Authority required listing to an Authority required (Streamlined) listing. No change to the Section 100 Highly Specialised Drugs Program listing is requested.

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New drug application (Minor submission)	Citrulline with carbohydrate, sachets, 4 g, Citrulline Amino Acid Supplement®  Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for urea cycle disorders including inborn errors of protein metabolism.
New drug application (Major submission)	Corifollitropin alfa, solution for injection, 100 micrograms in 0.5 mL pre-filled syringe, 150 micrograms in 0.5 mL pre-filled syringe, Elonva®  Schering-Plough Pty Ltd (MSD)	Fertility drug	Section 100 (IVF/GIFT Program) listing for patients who are receiving medical treatment as described in items 13200, 13201 or 13202 of the Medicare Benefits Schedule.
Change to listing (Major submission)	Dalteparin sodium, single dose pre-filled syringes, 7,500 IU (anti-Xa) in 0.75 mL, 10,000 IU (anti-Xa) in 1 mL, 12,500 IU (anti-Xa) in 0.5 mL, 15,000 IU (anti-Xa) in 0.6 mL and 18,000 IU (anti-Xa) in 0.72 mL, Fragmin®  Pfizer Australia Pty Ltd	Anti-blood clotting agent	Restricted benefit listing for: 1) Treatment of symptomatic venous thromboembolism (VTE) in patients with active solid tumour cancers; and 2) Secondary prevention of VTE in patients with active solid tumour cancers and previous VTE.
New drug application (Major submission)	Dronedarone hydrochloride, tablet, 400 mg, Multaq®  Sanofi-Aventis Australia Pty Ltd	Abnormal heart rhythms	Authority required (Streamlined) listing for the treatment of paroxysmal or persistent atrial fibrillation or flutter in addition to standard therapy in patients with at least one additional cardiovascular risk factor.
New drug application (Major submission)	Dutasteride with tamsulosin hydrochloride, capsules, 500 microgram – 400 microgram, Duodart®  GlaxoSmithKline Australia Pty Ltd	Symptoms associated with an enlarged prostate gland	Authority required (Streamlined) listing for the treatment of moderate to severe lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist.
New drug application (Major submission)	Eltrombopag olamine, tablets, 25 mg and 50 mg, Revolade®  GlaxoSmithKline Australia Pty Ltd	Idiopathic thrombocytopenia purpura (ITP) – a bleeding disorder	Section 100 (Highly Specialised Drugs Program) listing for adult patients with chronic immune (idiopathic) thrombocytopenia meeting certain criteria.
Re-submission (Minor submission)	Esomeprazole magnesium trihydrate, tablet (enteric coated), equivalent to 40 mg esomeprazole, Nexium®  AstraZeneca Pty Ltd	Acid related disorders, such as gastro-oesophageal reflux	Requests removal of the words "...and or repeats" from the NOTE, to allow an increase number of repeats to be prescribed for the healing of gastro-oesophageal reflux disease listing.

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Re-submission (Minor submission)	Everolimus, tablet, 5 mg and 10 mg, Afinitor®  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 (Major submission)	Ezetimibe, tablet, 10 mg, Ezetrol®  Merck Sharp & Dohme (Australia) Pty Ltd	High cholesterol levels	Requests extending the current Authority Required (Streamlined) listing definition of 'inadequate control' to allow the addition of ezetimibe to 20 mg of rosuvastatin or atorvastatin as opposed to the current "...40 mg or above of a statin".
New drug application (Minor submission)	Filgrastim (rbe), injection, single use pre-filled syringe, 120 micrograms in 0.2 mL, 300 micrograms in 0.5 mL, 480 micrograms in 0.5 mL, Nivestim®  Hospira Australia Pty Ltd	Blood cell stimulator	Requests listing for the same indications as the currently listed filgrastim product.
New drug application (Minor submission)	Fluconazole, powder for oral suspension, 50 mg in 5 mL, 35 mL, Diflucan®  Pfizer Australia Pty Ltd	Anti-infective	Requests listing of an oral suspension form for the same indications as the capsule and I.V. forms
Change to listing (Major submission)	Gefitinib, tablet, 250 mg, Iressa®  AstraZeneca Pty Ltd	Anti-cancer drug	Authority required listing for the first-line treatment, as monotherapy, of non-small cell lung cancer in patients with an activating mutation of the EGFR gene.
New drug application (Major submission)	Haemophilus influenza type b and group C Meningococcal polysaccharide conjugate vaccine, lyophilised powder for injection, 1 vial with 0.5 mL pre-filled syringe diluent, 10 vials with 10 0.5 mL pre-filled syringe diluent, Menitorix®  GlaxoSmithKline Australia Pty Ltd	Childhood vaccination against diseases caused by <i>H. influenza</i> and <i>N. meningitis C</i>	National Immunisation Program listing for the active immunisation of all Australian children, at 12 months of age, for the prevention of diseases caused by <i>Haemophilus influenzae</i> and <i>Neisseria meningitis serogroup C</i> .

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New drug application (Major submission)	Indacaterol maleate, capsule containing powder for oral inhalation, 150 micrograms and 300 micrograms, Onbrez®  Novartis Pharmaceuticals Australia Pty Ltd	Chronic obstructive pulmonary disease (airways obstruction)	Restricted benefit listing for the treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease.
Re-submission (Minor submission)	Levodopa with carbidopa (as monohydrate), intestinal gel, 20 mg-5 mg per mL, 100 mL, Duodopa®  Abbott Australasia Pty Ltd	Parkinson disease	Section 100 Highly Specialised Drugs Program (Public and Private Hospital authority Required) listing for the treatment of advanced Parkinson disease in patients who meets certain criteria; and for an Authority Required listing for maintenance therapy in advanced Parkinson disease in patients who meet certain criteria.
New drug application (Major submission)	Liraglutide (rys), solution for injection in 3 mL pre-filled injection pen, 2 pen pack and 3 pen pack, 6 mg in mL, Victoza®  Novo Nordisk Pharmaceuticals Pty Ltd	Type 2 diabetes	Authority required (Streamlined) listing for type 2 diabetes mellitus patients as: 1) Combination therapy with metformin and a sulfonylurea (triple therapy) 2) Combination therapy with metformin or a sulfonylurea (dual therapy).
Re-submission (Minor submission)	Meloxicam, tablet, 7.5 mg and 15 mg, Moxicam®  Alphapharm Pty Ltd	Anti-inflammatory	Requests the addition of a brand equivalence indicator between meloxicam tablets and meloxicam capsules.
Change to listing (Minor submission)	Nafarelin, nasal spray (pump pack), 200 micrograms (base) per dose (60 doses), (as acetate), Synarel®  Pfizer Australia Pty Ltd	Fertility drug	Request a Section 100 IVF/GIFT Program listing for the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, who meet certain criteria.
New drug application (Minor submission)	Olanzapine, wafer, 15 mg and 20 mg, Zyprexa Zydis®  Eli Lilly Australia Pty Ltd	Schizophrenia Bipolar disorder	Requests listing of two higher strengths of olanzapine in wafer form with the same indications as the lower strength tablets and wafers.
Re-submission (Major submission)	Omalizumab, powder for subcutaneous injection, 150 mg, Xolair®  Novartis Pharmaceuticals Australia Pty Ltd	Severe allergic asthma	Section 100 (Highly Specialised Drugs Program) Public and Private hospital Authority required listing for uncontrolled, severe allergic asthma in patients who meet certain criteria.

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New drug application (Major submission)	Omega-3-acid ethyl esters 90, capsules, 1,000 mg, Omacor®  Abbott Products Pty Ltd	Prevention against further heart attacks	Restricted benefit listing as adjuvant treatment in secondary prevention after myocardial infarction.
New drug application (Minor submission)	Ondansetron, tablet (dispersible), 4 mg and 8 mg, Ondansetron ODT-DRLA®  Dr Reddy's Laboratories (Australia) Pty Ltd	Nausea and vomiting associated with cancer treatment.	Requests listing of an orally disintegrating form of ondansetron tablets with a NOTE stating bioequivalence to the wafer form..
Change to listing (Minor submission)	Oxybutynin, transdermal patch, 36 mg (releasing approximately 3.9 mg per 24 hours), Oxytrol®  Hospira Australia Pty Ltd  Solifenacin, tablet, 5 mg and 10 mg, (as succinate), Vesicare®  Sigma Pharmaceuticals (Australia) Pty Ltd	Urinary incontinence	The sponsor of oxybutynin requests that the recommended restriction for solifenacin be changed from "...can not tolerate oral oxybutynin" to "...can not tolerate oxybutynin".
Re-submission (Minor submission)	Oxycodone (as hydrochloride) with NALOXONE (as hydrochloride) dehydrate, tablet, 5 mg-2.5 mg, 10 mg-5 mg, 20 mg-10 mg and 40 mg-20 mg (controlled release), Targin®  Mundipharma Pty Ltd	Severe pain	Restricted benefit listing for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.
New drug application (Major submission)	Paliperidone palmitate, aqueous suspension for injection, pre-filled syringe, 25 mg, 50 mg, 75 mg, 100 mg and 150 mg, Invega Sustenna®  Janssen-Cilag Pty Ltd	Schizophrenia	Authority required (Streamlined) listing for the treatment of schizophrenia.
New drug application (Major submission)	Plerixafor, solution for subcutaneous injection, 20 mg per mL, 1.2 mL, Mozobil®  Genzyme Australasia Pty Ltd	Anti-cancer drug	Section 100 (Highly Specialised Drugs Program) listing for the treatment of patients with non-Hodgkin lymphoma, Hodgkin lymphoma and multiple myeloma meeting certain criteria.

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Change to listing (Major submission)	Pneumococcal conjugate vaccine, 13 valent, pre-filled syringe, 0.5 mL, 1 vial and 10 vial packs, Prevenar 13 <sup>®</sup>  Wyeth Australia Pty Ltd	Vaccine for Pneumococcal disease	National Immunisation Program listing as a single dose for children under 3 years of age who have completed primary vaccination with Prevenar <sup>®</sup> .
Re-submission (Major submission)	Quetiapine fumarate, tablets, 25 mg, 100 mg, 200 mg and 300 mg (Seroquel <sup>®</sup> ), modified release tablets, 50 mg, 200 mg, 300 mg and 400 mg, Seroquel XR <sup>®</sup>  AstraZeneca Pty Ltd	Bipolar disorder	Authority required (Streamlined) listing for use as adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder. If recommended for depressive episodes associated with bipolar disorder (see item 7.4), the submission requests a simplified, Authority required (Streamlined) listing for the treatment of bipolar disorder.
Re-submission (Major submission)	Quetiapine fumarate, tablets, 25 mg, 100 mg, 200 mg and 300 mg, Seroquel <sup>®</sup> , modified release tablets, 50 mg, 200 mg, 300 mg and 400 mg (Seroquel XR <sup>®</sup> )  AstraZeneca Pty Ltd	Bipolar disorder	Authority required (Streamlined) listing for depressive episodes associated with bipolar disorder. If recommended for adjunctive therapy in acute mania associated with bipolar disorder (see item 7.3), the submission requests a simplified, Authority required (Streamlined) listing for the treatment of bipolar disorder.
Re-submission (Major submission)	Rituximab, solution for I.V. infusion, 100 mg in 10 mL and 500 mg in 50 mL (Mabthera <sup>®</sup> )  Roche Products Pty Ltd	Anti-cancer drug	Authority Required and Section 100 (Chemotherapy Pharmaceutical Access Program) listing for the treatment of CD20 positive, chronic lymphocytic leukaemia, in combination with chemotherapy.
Change to listing (Major submission)	Rosuvastatin, tablet, 20 mg (as calcium), Crestor <sup>®</sup>  AstraZeneca Pty Ltd	High cholesterol levels and the prevention of cardiovascular events.	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 CVD, diabetes, chronic inflammatory conditions nor active infection.
Re-submission (Minor submission)	Tamsulosin hydrochloride, tablet (prolonged release), 400 micrograms, Flomaxtra <sup>®</sup>  CSL Biotherapies	Symptoms associated with an enlarged prostate gland	Restricted benefit listing for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.

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New drug application (Minor submission)	Vildagliptin with metformin, tablet, 50-500 mg, 50-850 mg and 50-1000 mg, Galvumet®  Novartis Pharmaceuticals Australia Pty Ltd	Type 2 diabetes	Authority required (Streamlined) listing for the treatment of type 2 diabetes.
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