PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2011 PBAC MEETING

Closing date for consumer comments 9 February 2011

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
MARCH 2011 PBAC MEETING

Closing date for consumer comments 9 February 2011

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)*
Re-submission (Minor submission)	AMINO ACIDS - SYNTHETIC, FORMULA, compound powder, 400 g, Neocate Nutra® Nutricia Australia Pty Ltd	Medicinal food	Authority required listing for use in a child meeting certain criteria in the following conditions: - combined intolerance (not infant colic) to cow's milk protein, soy protein and protein hydrosylate formulas - severe intolerance (not infant colic) to cows' milk protein - severe intestinal malabsorption including short bowel syndrome
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	Extend the current Authority Required Section 85 and Section 100 listing under the Chemotherapy Pharmaceuticals Access Program (CPAP) to include initial treatment in combination with carboplatin and paclitaxel of a patient with advanced or metastatic non–squamous non–small cell lung cancer (NSCLC) with a WHO performance status of 0 or 1, who has not previously received treatment for their metastatic disease. Continuing treatment as monotherapy in a patient who does not have progressive disease.
Re-submission (Major submission)	BORTEZOMIB, powder for injection, 1 mg (solvent required), Velcade® Janssen – Cilag Pty Ltd	Multiple myeloma	Extend the current Authority Required listing to include the initial and continuing treatment as monotherapy or in combination with a corticosteroid and melphalan or cyclophosphamide in a patient with symptomatic multiple myeloma (1) who has severe renal impairment (GFR $\leq$ 30, after adequate hydration) and is newly diagnosed and receiving bortezomib as front line therapy, or (2) who commenced treatment on thalidomide with a resultant GFR drop to $\leq$ 30
New drug application (Minor submission)	BUPRENORPHINE with NALOXONE, soluble film (sublingual), 2 mg (as hydrochloride) - 0.5 mg (as hydrochloride), 8 mg (as hydrochloride) - 2 mg (as hydrochloride), Suboxone® Reckitt Benckiser (Australia) Pty Ltd	Opiate Dependence	Requests the same Section 100 (Opiate Dependence Treatment Program) Restricted benefit listing as the sublingual tablets for the new sublingual soluble film form.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2011 PBAC MEETING

Closing date for consumer comments 9 February 2011

Change to listing (Major submission)	CAPECITABINE, tablets, 150 mg and 500 mg, Xeloda® Roche Products Pty Ltd	Anti–cancer drug	Change the current Authority Required restriction for the adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour to include 'either as monotherapy or in combination with oxaliplatin' or remain unchanged. Change the wording of the current restriction for oxaliplatin adjuvant treatment to "adjuvant treatment of stage III (Dukes C) colon cancer, in combination with a fluoropyrimidine agent" instead of in combination with 5–fluorouracil and folinic acid.
New drug application (Major submission)	CLADRIBINE, tablet, 10 mg, Movectro® Merck Serono Australia Pty Ltd	Multiple sclerosis	Section 100 listing for the initial and continuing treatment of relapsing – remitting multiple sclerosis (RRMS) initiated by a neurologist, in an ambulatory patient who has experienced at least two documented attacks of neurological dysfunction, believed to be due to multiple sclerosis in the preceding two years who meets certain criteria.
New drug application (Major submission)	COLISTIMETHATE SODIUM, powder for nebuliser solution, 1 million IU (equivalent to 80 mg colistimethate sodium), Tadim® Phebra Pty Ltd	Inhaled antibiotic for the treatment of lung infections in patients with cystic fibrosis	Section 100 and Section 85 Authority Required listings for the treatment of colonisation and infections of the lung due to susceptible Pseudomonas aeruginosa in patients with cystic fibrosis.
Change to listing (Major submission)	DABIGATRAN ETEXILATE, capsules, 110 mg and 150 mg (as mesilate), Pradaxa® Boehringer Ingelheim Pty Ltd	Anti-thrombotic and anti-coagulant	Extend the current Authority Required listing to include the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation who are at moderate to high risk of developing stroke or systemic embolism, who meet certain criteria. The submission requests an Authority Required (STREAMLINED) listing for this indication.
Change to listing (Minor submission)	DALTEPARIN sodium, injection, 2,500 units (anti-Xa) in 0.2 mL, 5,000 units (anti-Xa) in 0.2 mL, 12,500 units (anti-Xa) in 0.5 mL, single dose pre-filled syringe, Fragmin® Pfizer Australia Pty Ltd	Anti-coagulant	Requests maximum quantities of the 2,500 and 5,000 strengths be increased from 10 to 20 with Nil repeats. Unrestricted benefit listing for a new 12,500 strength.
New drug application (Minor submission)	DOCETAXEL, solution concentrate for IV infusion, 20 mg in 1 mL, 80 mg in 4 mL, 140 mg in 7 mL, Docetaxel Actavis® Generic Health Pty Ltd	Anti-cancer drug	Authority required listing for monotherapy indications only.

Closing date for consumer comments 9 February 2011

Re-submission (Minor submission)	ELTROMBOPAG, tablets, 25 mg and 50 mg (as olamine), Revolade® GlaxoSmithKline Australia Pty Ltd	Idiopathic thrombocytopenia purpura (ITP) – a bleeding disorder	Resubmission for a Section 100 (Highly Specialised Drugs Program) Public and Private hospital authority required listing for severe thrombocytopenia in adult patients with severe chronic immune (idiopathic) thrombocytopenic purpua (ITP) meeting certain criteria.
Change to listing (Minor submission)	EZETIMIBE, tablet, 10 mg, Ezetrol® Merck Sharp & Dohme (Australia) Pty Ltd	High cholesterol levels	Requests a change to the restriction wording recommended at the November 2010 PBAC meeting to allow treatment of a patient with inadequate control after at least 3 months of treatment with 40 mg or greater of a statin, or at a maximum tolerated dose of a statin.
New drug application (Minor submission)	FENTANYL, transdermal patch, 1.28 mg (releasing approximately 12.5 micrograms per hour), 2.55 mg (releasing approximately 25 micrograms per hour), 5.10 mg (releasing approximately 50 micrograms per hour), 7.65 mg (releasing approximately 75 micrograms per hour), 10.20 mg (releasing approximately 100 micrograms per hour), Denpax® Alphapharm Pty Ltd	Severe pain	Restricted Benefit listing of a different brand of fentanyl patch which releases the same amount of fentanyl per hour but has a different amount of drug in the reservoir compared with the originator brand (Durogesic®)
New drug application (Minor submission)	FERROUS FUMARATE, tablet, 200 mg, (equivalent to 65.7 mg elemental iron), Ferro-Tab® AFT Pharmaceuticals Pty Ltd	Iron supplement for anaemia	Unrestricted benefit listing.
New drug application (Major submission)	FINGOLIMOD, capsule, 0.5 mg (as hydrochloride), Gilenya® Novartis Pharmaceuticals Australia Pty Ltd	Multiple sclerosis	Authority Required listing for the initial and continuing treatment of clinically relapsing-remitting multiple sclerosis (RRMS) in an ambulatory patient who has experienced at least two documented attacks of neurological dysfunction, believed to be due to multiple sclerosis in the preceding two years who meets certain criteria.
New drug application (Minor submission)	FOSAPREPITANT, powder for I.V. infusion, 150 mg, (as dimeglumine), Emend IV® Merck Sharp and Dohme (Australia) Pty Ltd	Anti-emetic	Authority required (STREAMLINED) listing for management of nausea and vomiting associated with cytotoxic chemotherapy (moderately emetogenic, highly emetogenic and combination anthracycline/cyclophosphamide regimens for breast cancer).

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2011 PBAC MEETING

Closing date for consumer comments 9 February 2011

Re-submission (Minor submission)	IMATINIB, tablets, 100mg and 400 mg, (as mesylate), Glivec® Novartis Pharmaceuticals Australia Pty Ltd	Anti-cancer drug	Resubmission for an 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 (Minor submission)	ISOTRETINOIN, capsules, 20 mg (30), 40 mg (60), Oratane® Ascent Pharma Pty Ltd	Severe acne	Requests the same Authority required (STREAMLINED) listing for two new pack sizes.
Change to listing (Major submission)	LENALIDOMIDE, capsules, 5 mg and 10 mg, Revlimid® Celgene Pty Ltd	Myelodysplastic syndrome	Extend the current Section 100 listing to include initial and continuing treatment of: - myelodysplastic syndrome (MDS) classified as low risk or or Intermediate–1 according to the International Prognostic Scoring System (IPSS); and - who has a deletion 5q cytogenic abnormality with or without additional cytogenic abnormalities; and - who is red blood cell transfusion dependent, and who meets certain criteria
New drug application (Major submission)	MANNITOL, capsule containing powder for oral inhalation, 40 mg (for use in inhaler device), Bronchitol® Pharmaxis Ltd	Cystic fibrosis	Section 100 (Highly Specialised Drugs) listing for the treatment of cystic fibrosis (CF) in paediatric (six years and above) and adult patients as either add on therapy to dornase alpha or in patients intolerant or in patients inadequately responsive to dornase alpha.
Re-submission (Major submission)	PARICALCITOL, capsules, 1 microgram and 2 microgram, Zemplar® Abbott Australasia Pty Ltd	Hyperparathyroidism	Resubmission for an Authority Required listing for treatment of secondary hyperparathyroidism in patients with chronic kidney disease where treatment with calcitriol is not appropriate.
Change to listing (Minor submission)	PEGFILGRASTIM, injection 6 mg in 0.6 mL, single use pre-filled syringe, Neulasta® Amgen Australia Pty Ltd	Bone marrow cell stimulator	Extend the current Section 100 (Highly Speciallised Drugs Program) Authority required listing to include primary prophylaxis of febrile neutropenia in Hodgkin Disease patients treated with escalated BEACOPP chemotherapy.
New drug application (Major submission)	PREGABALIN, capsules, 25 mg, 75 mg, 150 mg and 300 mg, Lyrica®	Neuropathic (nerve) pain	Authority Required (STREAMLINED) listing for the initial and continuing treatment of neuropathic pain including patients requiring dosage reduction due to renal impairment.

	Pfizer Australia Pty Ltd		
Change to listing (Major submission)	QUADRIVALENT HUMAN PAPILLOMAVIRUS (TYPES 6, 11, 16, 18) recombinant vaccine, solution for injection, 0.5 mL, solution for injection pre-filled syringe single dose, Gardasil® CSL Limited	Vaccine for prevention of human papillomavirus (HPV)	Extend the current listing of Gardasil on the National Immunisation Program (NIP) to include prevention of human papillomavirus (HPV) in males 12–13 years of age and a catch–up program over 2 years for Year 9 males.
Change to listing (Major submission)	RISPERIDONE, powder for I.M. injection, 25 mg, 37.5 mg and 50 mg (modified release), with 2 mL diluent in pre–filled syringe, Risperdal Consta® Janssen – Cilag Pty Ltd	Bipolar disorder	Extend the current Authority Required (STREAMLINED) listing to include maintenance treatment, in combination with a mood stabiliser, of treatment refractory bipolar 1 disorder.
New drug application (Major submission)	SERTINDOLE, tablets, 4 mg, 12 mg, 16 mg and 20 mg, Serdolect® Lundbeck Australia Pty Ltd	Schizophrenia	Authority Required (STREAMLINED) listing for the treatment of schizophrenia in people who have had prior treatment with one other anti–psychotic.
New drug application (Major submission)	TAPENTADOL HYDROCHLORIDE, tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg (as hydrochloride) (sustained release), Palexia SR® CSL Limited	Severe pain	Restricted Benefit listing for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.
New drug application (Major submission)	TELMISARTAN with AMLODIPINE, tablets, 40 mg–5 mg, 40 mg–10 mg, 80 mg–5 mg and 80 mg–10 mg (as besylate), Twynsta® Boehringer Ingelheim Pty Ltd	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in a patient who is not adequately controlled with either of the drugs in the combination.
Re-submission (Major submission)	TOBRAMYCIN, nebuliser solution single dose units, 300 mg in 5 mL, 56, Tobi® Novartis Pharmaceuticals Australia Pty Ltd	Inhaled antibiotic for the treatment of lung infections in patients with cystic fibrosis	Resubmission seeking a Section 100 listing for treatment of a patient with cystic fibrosis and pulmonary infection with Pseudomonas aeruginosa initiated by a specialist physician or paediatrician in consultation with a cystic fibrosis clinic/centre and who met certain criteria.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2011 PBAC MEETING

Closing date for consumer comments 9 February 2011

Change to listing (Minor submission)	VARENICLINE, box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack, Champix® Pfizer Australia Pty Ltd	Smoking Cessation	Requests to amend the NOTE of the current restriction to allow re-treatment 6 months from the commencement of a course of varenicline with another course of PBS-subsidised smoking cessation treatment.
New drug application (Major submission)	VORINOSTAT, capsule, 100 mg, Zolinza® Merck Sharp & Dohme (Australia) Pty Ltd	Anti–cancer drug	Authority Required listing for the initial and continuing treatment as monotherapy of advanced (stage IIB – IV) Cutaneous T-Cell Lymphoma (CTCL) where treatment failure has occurred with four systemic therapies, unless contraindicated. At least one of these therapies should be a chemotherapy regimen.