PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2012 PBAC MEETING

Closing date for consumer comments 8 February 2012

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 *(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)	Abiraterone, tablet, 250 mg (as acetate), Zytiga® Janssen-Cilag Pty Ltd	Metastatic prostate cancer	Re-submission for an Authority Required listing for the initial and continuing treatment, in combination with prednisone or prednisolone, of patients with metastatic advanced prostate cancer (castration resistant prostate cancer) in whom disease progression has occurred following treatment with docetaxel.
New drug application (Major submission)	Aflibercept, solution for intravitreal injection, 40 mg per mL, Eylea® Bayer Australia Ltd	Age-related macular degeneration	Authority Required listing for the initial and continuing treatment, by an ophthalmologist, as sole subsidised therapy, of a patient with subfoveal choroidal neovascularisation (CNV) due to age related macular degeneration (AMD), as diagnosed by fluorescein angiography.
Re-submission (Major submission)	Agomelatine, tablet, 25 mg, Valdoxan® Servier Laboratories (Australia) Pty Ltd	Anti-depressant	Resubmission for a Restricted Benefit listing for major depressive disorders.
Change to listing (Minor submission)	Amino acid – synthetic, formula, compound powder 400 g, Neocate LCP+MCT® Amino acid – synthetic, formula, compound powder 400 g, Neocate Advance Vanilla® Nutricia Australia Pty Ltd	Medicinal foods	Authority required listing for initial and continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in patients 18 years of age or less with eosinophilic oesophagitis who require an amino acid based formula as a component of a dietary elimination programme and who meet certain criteria.
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without methionine, oral liquid 125 mL, 30, HCU Lophlex LQ® Nutricia Australia Pty Ltd	Medicinal food	Restricted benefit listing for pyridoxine non-responsive homocystinuria.

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New drug application (Minor submission)	Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, oral liquid, 130 mL, 30, MMA/PA Cooler® Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for methylmalonic acidaemia and propionic acidaemia.
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, oral liquid 125 mL, 30, TYR Lophlex LQ® Nutricia Australia Pty Ltd	Medicinal Food	Restricted benefit listing for tyrosinaemia.
Change to listing (Minor submission)	Amino acid formula with vitamins and minerals without phenylalanine, oral liquid 125 mL, PKU Lophlex LQ 20® Nutricia Australia Pty Ltd	Medicinal food	Request to replace one flavour and add one new flavour to the existing range of flavours, and to inform the PBAC of minor nutrient changes in the new flavour products. No change to the current PBS listing is requested.

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Change to listing (Minor submission)	Amino acid formula with vitamins and minerals without phenylalanine, sachets 25 g, 30, PKU Express 15® Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, sachets 25 g, 30, MSUD Express 15® Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, sachets 25 g, 30, TYR Express 15® Amino acid formula with vitamins and minerals without methionine, sachets 25 g, 30, HCU Express 15® Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, sachets 25 g, 30, MMA/PA Express 15® Amino acid formula with vitamins and minerals without lysine and low in tryptophan, sachets 25 g, 30, GA Express 15® Vitaflo Australia Pty Ltd	Medicinal foods	Requests to change the name of the current 'Express' range of amino acid formulae to "XXX Express 15" to denote the amount of protein contained in each sachet. To advise of amendments to the vitamin, mineral and trace element profile of the 'Express' range of products.
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without phenylalanine, sachets 34 g, 30, PKU Express 20® Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, sachets 34 g, 30, MSUD Express 20® Vitaflo Australia Pty Ltd	Medicinal Foods	Restricted benefit listing for phenylketonuria for a new pack size to provide 20 g protein per sachet. (PKU Express 20) Restricted benefit listing for maple syrup urine disease for a new pack size to provide 20 g protein per sachet. (MSUD Express 20)
New drug application (Minor submission)	Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, oral liquid 125 mL, 30, MSUD Lophlex LQ® Nutricia Australia Pty Ltd	Medicinal food	Restricted benefit listing for maple syrup urine disease.

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New drug application and change to listing (Minor submission)	Apixaban, tablet 2.5 mg, Eliquis® Bristol-Myers Squibb Australia Pty Ltd	Anti-thrombotic drug	Requests Authority Required listings of 20 and 30 tablet packs for the prevention of venous thromboembolism in patients undergoing total hip replacement.
Re-submission (Major submission)	Boceprevir, capsule, 200 mg, Victrelis® Merck Sharp & Dohme (Australia) Pty Ltd	Hepatitis C	Re-submission for Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for treatment of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who are naïve or who have failed one prior attempt with interferon alfa or peginterferon alfa treatment for hepatitis C and meet certain criteria.
Change to listing (Major submission)	Bortezomib, powder for injection 1 mg (solvent required), Velcade® Janssen-Cilag Pty Ltd	Anti-cancer drug for multiple myeloma	Extend the current Authority Required listing to include induction therapy in patients with newly diagnosed symptomatic multiple myeloma who are eligible for high dose chemotherapy, as part of combination therapy.
Re-submission (Minor submission)	Cabazitaxel, solution concentrate for I.V. infusion, 60 mg in 1.5 mL, Jevtana® Sanofi-Aventis Australia Pty Ltd	Metastatic prostate cancer	Resubmission for an Authority Required listing for treatment of hormone refractory metastatic carcinoma of the prostate in patients previously treated with a docetaxel containing regimen.
New drug application (Minor submission)	Carbomer and triglyceride lipids, eye gel, 2 mg-10 mg per g (0.2%-1%), 10 g and single dose units 0.6 g, 30, Artelac® Gel Tears Bausch & Lomb (Australia) Pty Ltd	Ocular lubricant	1. For the multi-dose presentation: Restricted benefit listing in the general and optometrical schedules for severe dry eye syndrome, including Sjogren's syndrome; 2. For the single dose unit presentation: Authority Required (Streamlined) and Authority Required listings in the general and optometrical schedules respectively for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

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New drug application (Major submission)	Dapagliflozin, tablet, 10 mg (as propanediol monohydrate), (brand name-to be assigned) Bristol-Myers Squibb Australia Pty Ltd	Type 2 diabetes	Authority Required (Streamlined) listing for treatment of type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.
New drug application (Major submission)	Dapagliflozin, tablet, 10 mg (as propanediol monohydrate), (brand name-to be assigned) Bristol-Myers Squibb Australia Pty Ltd	Type 2 diabetes	Authority Required (Streamlined) listing for the treatment of type 2 diabetes, in combination with metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of dapagliflozin despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.
Change to listing (Minor submission)	Denosumab, injection 120 mg in 1.7 mL, Xgeva® Amgen Australia Pty Ltd	Bone metastases from prostate cancer	Requests a change to the restriction wording for the Authority Required listing for bone metastases from hormone resistant prostate cancer to either: Option 1: Bone metastases from castrate-resistant prostate cancer OR Option 2: Bone metastases from prostate cancer.
Change to listing (Major submission)	Denosumab, injection 60 mg in 1 mL pre-filled syringe, Prolia® Amgen Australia Pty Ltd	Osteoporosis	Change the Authority Required (Streamlined) listing for treatment as the sole PBS subsidised anti-resorptive agent for osteoporosis in a woman aged 70 years or older from patients with a Bone Mineral Density (BMD) T-score of -3.0 or less to patients with a BMD T-score of -2.5 or less
Change to listing (Major submission)	Etanercept, injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL; injections 50 mg in 1 mL single use pre-filled syringes; injection 50 mg in 1 mL single use auto-injector, Enbrel® Pfizer Australia Pty Ltd	Chronic plaque psoriasis	Extend the current Authority Required listing to include the initial and continuing treatment of severe chronic plaque psoriasis in a patient less than 18 years of age who meets certain criteria.

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Change to listing (Minor submission)	Etonogestrel, subcutaneous implant 68 mg, Implanon NXT® Merck Sharp & Dohme (Australia) Pty Ltd	Contraception	Request for inclusion in the PBS medicines for prescribing by authorised midwives.
Change to listing (Major submission)	Ezetimibe with simvastatin, tablet, 10 mg-20 mg, Vytorin® Merck Sharp & Dohme (Australia) Pty Ltd	Lipid lowering drug	Extend the current Authority Required (Streamlined) listing to include treatment, in conjunction with diet and exercise for the primary prevention of major cardiovascular events in patients with moderate to severe chronic kidney disease and who do not fall into a category for which the General Statement for Lipid Lowering Drugs allows PBS subsidised treatment with a statin.
Change to listing (Minor submission)	Fentanyl, lozenges, 200 micrograms, 400 micrograms, 600 micrograms, 800 micrograms, 1200 micrograms and 1600 micrograms (as citrate), Actiq® Aspen Pharma Pty Ltd	Analgesic	Requests listing of a 9-lozenge pack to replace the current 3-lozenge packs (listed with a maximum quantity of 3 packs of 3 lozenges) for dose titration for breakthrough pain in palliative care patients with cancer.
New drug application (Minor submission)	Follitropin alfa and lutropin alfa, powder for injection, 150 I.U.-75 I.U. with diluent, Pergoveris® Merck Serono Australia Pty Ltd	Fertility drug	1. Section 100- IVF/GIFT Program listing for patients with severe LH and FSH deficiency who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. 2. Restricted Benefit listing for anovulatory infertility in women with severe LH and FSH deficiency.
Change to listing (Minor submission)	Gefitinib, tablet 250 mg, Iressa® AstraZeneca Pty Ltd	Lung cancer	Request to: 1. Change the listing for locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less who meet certain criteria from an Authority Required (applications in writing, specialised drug) to a standard Authority Required listing; and 2. increase the number of repeats from 1 to 3.
New drug application (Major submission)	Human menopausal gonadotrophin , powder for injection, 600 units and 1200 units, with solvent Menopur® Ferring Pharmaceuticals Pty Ltd	Fertility drug	Section 100 (IVF/GIFT Program) listing for a patient who is receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medical Benefits Schedule.

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Re-submission (Minor submission)	Icatibant, injection, 30 mg in 3 mL (as acetate), single use pre-filled syringe, Firazyr® Shire Australia Pty Ltd	Hereditary angioedema	Re-submission for an Authority Required listing for the treatment of hereditary angioedema.
Change to listing (Major submission)	Imatinib, tablet, 100 mg and 400 mg, (as mesylate) Glivec® Novartis Pharmaceuticals Australia Pty Ltd	Anti-cancer drug	Change the current Authority required listing for the adjuvant treatment of a patient at high risk of recurrence following complete resection of primary gastrointestinal stromal tumour (GIST), which has been histologically confirmed by the detection of CD117 on immunohistochemical staining, at a dose not exceeding 400 mg per day, from a maximum duration of treatment of 12 months to a maximum duration of treatment of 3 years.
Re-submission (Major submission)	Ipilimumab, concentrate solution for I.V infusion, 50 mg in 10 mL, 200 mg in 40 mL, Yervoy® Bristol-Myers Squibb Australia Pty Ltd	Melanoma	Re-submission for Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for treatment of patients with unresectable stage III or stage IV malignant melanoma who have not responded to or were intolerant to prior systemic therapy for metastatic disease.
New drug application (Minor submission)	Linezolid, tablet, 600 mg, Zyvox® Pfizer Australia Pty Ltd	Antibiotic	Request to reinstate the rescinded PBAC recommendation for an Authority Required listing for treatment initiated in a hospital for infections due to microbiologically proven, multi-resistant methicillin-resistant Staphylococcus species, where no other antimicrobial agent can be used because of either: demonstrated treatment failure, or laboratory confirmed resistance, or intolerance or potential drug interactions.
Re-submission (Minor submission)	Mannitol, capsule containing powder for oral inhalation, 40 mg (for use in inhaler device), Bronchitol® Pharmaxis Ltd	Cystic fibrosis	Resubmission for an Authority Required listing, as monotherapy, for the treatment of cystic fibrosis in: 1) Patients who fail initiation criteria for dornase alfa; 2) Patients using dornase alfa intermittently; 3) Patients who are using dornase alfa, but are inadequately responsive, and it is considered may improve with mannitol as an alternative to dornase alfa.

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Re-submission (Major submission)	Naproxen with esomeprazole, tablet 500 mg -20 mg (as magnesium trihydrate), Vimovo® AstraZeneca Pty Ltd	Arthritis	Re-submission for a Restricted Benefit listing for the symptomatic treatment of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis in a patient who requires a non-steroidal anti-inflammatory drug and is at high risk of developing gastrointestinal complications.
Re-submission (Major submission)	Pazopanib, tablet, 200 mg and 400 mg (as hydrochloride), Votrient® GlaxoSmithKline Pty Ltd	Anti-cancer drug	Re-submission for an Authority Required listing for the initial and continuing treatment as the sole PBS subsidised tyrosine kinase inhibitor (TKI) therapy, of stage IV clear cell variant renal cell carcinoma in a newly diagnosed patient who meets the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group, has a WHO performance status of 2 or less.
New drug application (Major submission)	Pitavastatin, tablet, 1 mg, 2 mg and 4 mg (as calcium), Livalo® Abbott Australasia Pty Ltd	Lipid lowering drug	Restricted Benefit listing for use in patients who meet the criteria set out in the General Statement for Lipid Lowering Drugs.
Re-submission (Major submission)	Pregabalin, capsule, 25 mg, 75 mg, 150 mg and 300 mg, Lyrica® Pfizer Australia Pty Ltd	Neuropathic (nerve) pain	Re-submission for Authority Required (Streamlined) listings for: 1. Initiation and up-titration of treatment for neuropathic pain (75 mg) 2. Initiation of treatment for neuropathic pain in patients requiring a reduced dose due to renal impairment (25 mg) 3. Continuation of treatment in patients who have received a PBS prescription for initiation of treatment and have shown an adequate clinical response (all strengths) 4. Continuation of treatment in patients who had shown clinical response to pregabalin prior to PBS listing (all strengths)
Re-submission (Major submission)	Rasagiline, tablet, 1 mg (as mesilate), Azilect® Lundbeck Australia Pty Ltd	Parkinson disease	Re-submission for an Authority required (Streamlined) listing for the treatment of Parkinson disease as adjunctive therapy in a patient being treated with levodopa-decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect.

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New drug application (Major submission)	Rivaroxaban, tablet, 15 mg and 20 mg, Xarelto® Bayer Australia Ltd	Anti-thrombotic drug	Authority Required (Streamlined) listing for two new strengths, 15 mg and 20 mg, for the prevention of stroke and systemic embolism in a patient with non-valvular atrial fibrillation (NVAF), who is at risk of developing stroke or systemic embolism as evidenced by prior stroke (ischaemic or unknown type), TIA or non-CNS systemic embolism or two or more of the following risk factors: i. age ≥ 75 years; ii. hypertension; iii. diabetes mellitus; iv. heart failure and/or left ventricular ejection fraction ≤ 35%
New drug application (Major submission)	Rivaroxaban, tablet, 15 mg and 20 mg, Xarelto® Bayer Australia Ltd	Anti-thrombotic drug	Authority Required (Streamlined) listing for: 1. 15 mg tablets: Initial treatment of confirmed acute symptomatic deep vein thrombosis (DVT) without symptomatic pulmonary embolism (PE). 2. 20 mg tablets: Continuing treatment of confirmed acute symptomatic DVT without symptomatic PE, and for the prevention of recurrent venous thromboembolism (VTE) with appropriate treatment duration of up to two years, dependent on the risk of VTE recurrence.
Re-submission (Major submission)	Sunitinib, capsule, 12.5 mg, 25 mg and 50 mg (as malate), Sutent® Pfizer Australia Pty Ltd	Anti-cancer drug	Re-submission to extend the current Authority required listing to include initial and continuing treatment of metastatic, unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (or carcinoma) (pancreatic NET) in a patient who is symptomatic (despite somatostatin analogues) or has documented disease progression.
New drug application (Major submission)	Tafluprost, eye drops (preservative-free), 15 micrograms per mL (0.0015%), single dose units 0.3 mL, 30, Saflutan® Merck Sharp & Dohme (Australia) Pty Ltd	Glaucoma	Unrestricted benefit listing on the General and Optometrical Schedules, for the treatment of ocular hypertension and primary open-angle glaucoma.

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New drug application (Major submission)	Taliglucerase alfa, lyophilised powder for injection, 200 units, Elelyso® Pfizer Australia Pty Ltd	Gaucher disease	Section 100 (Highly Specialised Drugs Program) or Life Saving Drugs Program listing for the long-term enzyme replacement therapy for patients with a confirmed diagnosis of Gaucher disease.
Re-submission (Major submission)	Tapentadol, tablet, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg (as hydrochloride) (sustained release), Palexia SR® CSL Limited	Chronic severe pain	Re-submission for a Restricted Benefit listing for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.
New drug application (Major submission)	Telaprevir, tablet, 375 mg, Incivo® Janssen-Cilag Pty Ltd	Hepatitis C	Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for the treatment, in combination with peginterferon-alfa and ribavirin, of chronic genotype 1 hepatitis C in patients 18 years or older who have compensated liver disease and meet certain criteria.
Change to listing (Minor submission)	Teriparatide, injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen, Forteo® Eli Lilly Australia Pty Ltd	Osteoporosis	Request to change the current Authority Required listing (applications in writing, specialised drug) to a standard Authority Required listing.
New drug application (Minor submission)	Triglycerides – medium chain, formula, powder 400 g, LipiStart® Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit listing for chylous ascites; chylothorax; fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders; hyperlipoproteinaemia type 1 and long chain fatty acid oxidation disorders.
Re-submission (Minor submission)	Velaglucerase alfa, powder for I.V. infusion, 400 units in 4 mL, Vpriv® Shire Australia Pty Ltd	Gaucher disease	Resubmission requesting inclusion on the Life Saving Drugs Program (LSDP) for the treatment of type 1 Gaucher disease in patients who meets certain criteria.