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

Closing date for consumer comments 13 June 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 to request a review of the March 2012 PBAC recommendation 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 (Minor submission)	APREPITANT, capsule 165 mg, Emend® Merck Sharp & Dohme (Australia) Pty Limited	Anti-emetic	Authority Required (STREAMLINED) listing of a higher strength, single dose oral presentation with the same indications as the current PBS listing for the three day dose pack.
New drug application (Minor submission)	ATENOLOL, oral solution, 50 mg in 10 mL, 300 mL, Atenolol-AFT® AFT Pharmaceuticals	Antihypertensive	Restricted Benefit listing of an oral solution presentation for patients who cannot tolerate atenolol tablets.
Re-submission (Major submission)	AZTREONAM, powder for inhalation, 75 mg (as lysine), with diluent, Cayston® Gilead Sciences Pty Ltd	Cystic fibrosis	Re-submission for a Section100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for the management of a proven *P. aeruginosa* infection in patients with cystic fibrosis.

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Re-submission (Minor submission)	BOCEPREVIR, capsule, 200 mg, Victrelis® Merck Sharp & Dohme Australia Pty Ltd	Hepatitis C	Re-submission for a Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for treatment, managed by an accredited treatment centre, of chronic hepatitis C genotype 1 infection in combination with peginterferon alfa and ribavirin in patients 18 years or older who have compensated liver disease and who have received no prior or no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who meet certain criteria.
Change to listing (Major submission)	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX, lyophilised powder for injection, 100 units, Botox® Allergan Pty Ltd	Urinary incontinence	Extend the current Section 100 (Botulinum Toxin Program) listing to include the treatment of urinary incontinence due to neurogenic detrusor overactivity in patients who are not adequately managed by anticholinergic medication.
Re-submission (Major submission)	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX, lyophilised powder for injection, 100 units, Botox® Allergan Pty Ltd	Chronic migraine	Re-submission to extend the current Section 100 (Botulinum Toxin Program) listing to include the prophylaxis of headaches in adult patients with chronic migraine who meet certain criteria.
Re-submission (Minor submission)	DABIGATRAN ETEXILATE, capsules, 110 mg and 150 mg (as mesilate), Pradax Boehringer Ingelheim Pty Ltd	Anti-thrombotic and anti-coagulant	Sponsor comment on the March 2011 PBAC recommendation for an extension to the Authority Required listing to include the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation (NVAF) who are at moderate to high risk of developing stroke or systemic embolism, who meet certain criteria.
Change to listing (Minor submission)	DENOSUMAB, injection, 120 mg in 1.7 mL, Xgeva® Amgen Australia Pty Ltd	Bone metastases from prostate cancer or breast cancer	Change the current PBS listing from Authority Required for bone metastases from breast cancer or hormone-resistant prostate cancer to Authority Required (STREAMLINED).

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New drug application (Major submission)	DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE, eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), single dose units 0.6 mL, 60, Cosopt® Preservative Free Eye Drops Merck Sharp & Dohme (Australia) Pty Limited	Glaucoma and ocular hypertension	Restricted Benefit listings in the general and optometrical schedules for the reduction of elevated intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension that is not adequately controlled with monotherapy.
Re-submission (Minor submission)	ECULIZUMAB, solution concentrate for I.V. infusion, 300 mg in 30 mL, Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	Paroxysmal nocturnal haemoglobinuria	To provide data regarding eculizumab's dosing schedule for patients with paroxysmal nocturnal haemoglobinuria who are experiencing breakthrough haemolysis under the Life Saving Drugs Program.
Change to listing (Major submission)	ERLOTINIB, tablet, 25 mg, 100 mg, 150 mg (as hydrochloride), Tarceva® Roche Products Pty Limited	Lung cancer	Extend the Authority Required listing to include: Initial and continuing first-line treatment, as monotherapy, of locally advanced (stage IIIB) or metastatic (stage IV) non-small cell lung cancer (NSCLC) in patients with evidence of activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material who do not have progressive disease. *Or alternatively:* Initial and continuing first-line treatment, as monotherapy, of locally advanced (stage IIIB) or metastatic (stage IV) non squamous NSCLC or not otherwise specified NSCLC in patients with evidence of activating mutation(s) of the EGFR gene in tumour material who do not have progressive disease.
New drug application (Major submission)	EZETIMIBE with ATORVASTATIN, tablet, 10 mg-10 mg (as calcium), 10 mg-20 mg (as calcium), 10 mg-40 mg (as calcium), 10 mg-80 mg (as calcium), Atozet® EZETIMIBE and ATORVASTATIN, pack containing 30 tablets ezetimibe 10 mg, and 30 tablets atorvastatin 10 mg (as calcium), atorvastatin 20 mg (as calcium), atorvastatin 40 mg (as calcium) or atorvastatin 80 mg (as calcium), Ezetrol® Plus Atorva Merck, Sharp & Dohme (Australia) Pty Limited	High cholesterol	Authority Required (Streamlined) listing for the treatment, in conjunction with dietary therapy and exercise, for co-administration with a HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who meet certain criteria.

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Change to listing (Minor submission)	EZETIMIBE with SIMVASTATIN, tablet, 10 mg-10 mg, 10 mg-20 mg, Vytorin® Merck Sharp & Dohme (Australia) Pty Ltd	High cholesterol	Requests extension to the listing of the 10 mg-10 mg and 10 mg-20 mg strengths to include the additional indication of treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who meet certain criteria.
New drug application (Minor submission)	GLYCOMACROPEPTIDE with VITAMINS and MINERALS, ready-to-eat bar, 54 g per bar, 81g per bar, 7, Camino Pro® Complete™ with Glytactin™ GLYCOMACROPEPTIDE with VITAMINS and MINERALS, oral liquid, 500 mL, 12, Camino Pro® Restore™ with Glytactin™ GLYCOMACROPEPTIDE with VITAMINS and MINERALS, powder, 49 g, 28, Camino Pro® Bettermilk™ with Glytactin™ Cambrooke Australia Pty Ltd	Medicinal food	Restricted Benefit listing for phenylketonuria.
Re-submission (Major submission)	IVABRADINE, tablet, 5 mg and 7.5 mg (as hydrochloride), Coralan® Servier Laboratories (Australia) Pty Ltd	Heart failure	Re-submission for an Authority Required listing for the treatment of symptomatic systolic heart failure in patients in sinus rhythm, with a heart rate of at least 75 bpm, measured after 5 minutes rest, who are stabilised on optimal heart failure therapy, which must include an ACE inhibitor or angiotensin II antagonist and a beta blocker (unless intolerant or contraindicated).
Change to listing (Major submission)	LINAGLIPTIN, tablet, 5 mg, Trajenta® Boehringer Ingelheim Pty Ltd	Type 2 diabetes	Extend the current Authority Required (Streamlined) listing to include the treatment of patients with type 2 diabetes in combination with metformin and a sulfonylurea (triple oral therapy).
Change to listing (Major submission)	METHYLPHENIDATE HYDROCHLORIDE, tablet 18 mg, 27 mg, 36 mg, and 54 mg, (extended release) Concerta® Janssen-Cilag Pty Ltd	Attention deficit hyperactivity disorder in adults	Extend the current Authority Required listing to include use in patients diagnosed with attention deficit hyperactivity disorder (ADHD) after the age of 18 years.

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Re-submission (Major submission)	MYCOPHENOLATE SODIUM, tablet (enteric coated), 180 mg and 360 mg (mycophenolic acid), Myfortic® Novartis Pharmaceuticals Australia Pty Ltd	Lupus nephritis	Re-submission to extend the current Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) and general schedule Authority Required listings to include the treatment, initiated by or in consultation with a nephrologist, of patients with biopsy-proven WHO Class III, IV or V lupus nephritis.
Change to listing (Minor submission)	OLMESARTAN with AMLODIPINE, tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besylate), tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besylate), tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besylate), Sevikar® Merck Sharp & Dohme (Australia) Pty Ltd	Antihypertensive	Requests inclusion of PBS prescribing by nurse practitioners.
New drug application (Minor submission)	PHENOBARBITONE, injection, 219 mg in 1 mL (as sodium), Phenobarbitone Injection® Aspen Pharma Pty Ltd	Epilepsy	To replace the current PBS listed 200 mg in 1 mL strength injection with the 219 mg in 1 mL strength.
Re-submission (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.

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Re-submission (Major submission)	PLERIXAFOR, solution for injection, 20 mg in 1 mL, 1.2 mL, Mozobil Sanofi Aventis Australia Pty Ltd	Lymphoma and multiple myeloma	Re-submission for Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for: 1. Treatment, in combination with a granulocyte-colony stimulating factor (G-CSF), of lymphoma in patients who require autologous stem cell transplantation and who have failed previous stem cell collection or who are failing a current stem cell collection. 2. Treatment, in combination with a granulocyte-colony stimulating factor (G-CSF), of multiple myeloma in patients who require autologous stem cell transplantation and who have failed previous stem cell collection or who are failing a current stem cell collection.
Re-submission (Major submission)	PRUCALOPRIDE, tablet, 1 mg and 2 mg (as succinate), Resotrans® Janssen-Cilag Pty Ltd	Chronic constipation	Re-submission for a Restricted benefit listing for the treatment of chronic functional constipation in adults in whom laxatives fail to provide adequate relief. Before prucalopride is considered patients must have tried at least three different types of laxatives from different classes (such as bulk forming agents, osmotic laxatives, stimulant laxatives) for at least six months.
New drug application (Minor submission)	RETINOL PALMITATE, eye ointment 138 micrograms per g (250 IU per g Vitamin A), VitA-POS® AFT Pharmaceuticals Pty Limited	Ocular lubricant	Requests unrestricted benefit listings in the General and Optometric Schedules and a General Schedule Restricted benefit listing for use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.
Re-submission (Major submission)	RIFAXIMIN, tablet, 550 mg, Xifaxan® Norgine Pty Ltd	Hepatic encephalopathy (a brain disorder caused by chronic liver failure)	Re-submission for a Restricted benefit listing for the prevention of hepatic encephalopathy in adult patients who have had prior episodes of hepatic encephalopathy. Treatment is to be in combination with lactulose where lactulose therapy can be tolerated.

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Re-submission (Major submission)	SAPROPTERIN, soluble tablet, 100 mg (as dihydrochloride), Kuvan® Merck Serono Australia Pty Ltd	Hyperphenylalaninaemia in patients with tetrahydrobiopterin (BH4) deficiency (a genetic disorder where there is a shortage of BH4).	Re-submission for a Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for treatment of hyperphenylalaninaemia (HPA) in patients demonstrated to have tetrahydrobiopterin (BH4) deficiency. If rejected, Life Saving Drugs Program listing for BH4 deficiency is requested.
Change to listing (Major submission)	SAXAGLIPTIN, tablet, 5 mg, (as hydrochloride), Onglyza® Bristol-Myers Squibb Australia Pty Ltd	Type 2 diabetes	Extend the current Authority Required (Streamlined) listing to include the treatment of patients with type 2 diabetes in combination with insulin.
New drug application (Minor submission)	SODIUM HYALURONATE, eye drops, 1 mg per mL (0.1 %), Hylo®-Fresh SODIUM HYALURONATE, eye drops, 2 mg per mL (0.2 %), Hylo®-Forte AFT Pharmaceuticals Pty Limited	Ocular lubricant	Requests a General Schedule Authority Required (Streamlined) listing for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops and an Optometric Schedule Authority Required listing for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.
Change to listing (Major submission)	STRONTIUM RANELATE, sachet containing granules for oral suspension, 2g, Protos® Servier Laboratories (Australia) Pty Ltd	Osteoporosis	Extend the current Authority Required (Streamlined) listing for primary and secondary osteoporosis to include male patients.
Re-submission (Minor submission)	SUNITINIB, capsule, 12.5 mg, 25 mg, 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 patients who are symptomatic (despite somatostatin analogues) or who have documented disease progression.
Re-submission (Minor submission)	TAPENTADOL, tablet, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg (as hydrochloride) (sustained release), Palexia SR® CSL Biotherapies (CSL Limited)	Analgesic	Re-submission for a Restricted Benefit listing for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.

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Re-submission (Minor submission)	TELAPREVIR, tablet, 375 mg, Incivo® Janssen-Cilag Pty Ltd	Hepatitis C	Re-submission for a 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 and managed by an accredited treatment centre, of chronic hepatitis C genotype 1 infection in patients 18 years or older who have compensated liver disease and who meet certain criteria.
Change to listing (Major submission)	TRASTUZUMAB, powder for I.V infusion, 60 mg and 150 mg, Herceptin® Roche Products Pty Limited	Breast cancer	Extend the current Section 100 Efficient Funding of Chemotherapy (Public Hospital or Private Hospital/Clinic) listing to include: 1. Initial and continuing treatment of human epidermal growth factor receptor-2 (HER2) positive early breast cancer commencing concurrently with neoadjuvant chemotherapy; and 2. Initial and continuing treatment of HER2 positive locally advanced breast cancer commencing concurrently with neoadjuvant chemotherapy.
New drug application (Minor submission)	USTEKINUMAB (rmc), injection, 45 mg in 0.5 mL pre-filled syringe, Stelara® Janssen-Cilag Pty Ltd	Psoriasis	Requests listing of a pre-filled syringe presentation to replace the currently PBS listed single use vial presentation at the same price.
New drug application (Major submission)	VEMURAFENIB, tablet, 240 mg, Zelboraf® Roche Products Pty Limited	Melanoma	Authority Required listing for initial and continuing treatment of previously untreated unresectable stage IIIC or stage IV melanoma in patients positive for the serine/ threonine-protein kinase B-raf (BRAF) V600 mutation, or alternatively BRAF V600 mutation with an ECOG of 0 or 1, who do not have progressive disease.
New drug application (Minor submission)	ZOLEDRONIC ACID, solution for I.V infusion, 4 mg in 100 mL, Zometa® Novartis Pharmaceuticals Australia Pty Ltd	Bone metastases from prostate cancer or breast cancer, multiple myeloma, hypercalcaemia of malignancy	Section 100 (Highly Specialised Drugs Program) listing of a ready-to-use 4 mg in 100 mL presentation with the same indications as the current PBS listing for the 4 mg in 5 mL liquid concentrate for infusion at the same price.

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Review	ANTICOAGULANT THERAPIES IN ATRIAL FIBRILLATION	Atrial fibrillation	To inform the Government on options for improving the health outcomes of patients treated with anticoagulation therapies, including optimising the use of currently available treatments in Australia as well as the future role of newer therapies for the treatment of atrial fibrillation, such as dabigatran (Pradaxa®).
Review	STATINS REVIEW	High cholesterol	To seek advice from the PBAC on any new evidence whether or not two medicines, atorvastatin and rosuvastatin, should be included in the existing statins lipid-lowering medicines therapeutic group which includes simvastatin and pravastatin.