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

Closing date for consumer comments 10 October 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 (Major submission)	ABIRATERONE, tablet, 250 mg (as acetate), Zytiga® Janssen-Cilag Pty Ltd	Prostate cancer	Requests a review of the PBAC's March 2012 recommendation to list abiraterone on a cost-minimisation basis to cabazitaxel as an Authority Required benefit for the treatment, in combination with prednisone or prednisolone, of castration resistant metastatic carcinoma of the prostate in a patient who meets certain criteria.
Re-submission (Major submission)	ALGLUCOSIDASE alfa-rch, powder for I.V. infusion, 50 mg, Myozyme® Genzyme (Sanofi-Aventis Australia)	Pompé disease	To provide the PBAC with additional data to demonstrate that alglucosidase alfa meets criterion 4 of the Life Saving Drugs Program for the treatment of patients with late-onset Pompé disease.
Change to listing (Major submission)	APIXABAN, tablets, 2.5 mg and 5 mg, Eliquis® Bristol-Myers Squibb Australia Pty Ltd	Anti-thrombotic drug	Extend the current Authority Required listing to include an Authority Required (Streamlined) listing for the prevention of stroke or systemic embolism in a patient with non-valvular atrial fibrillation who meets certain criteria.
Change to listing (Minor submission)	APOMORPHINE HYDROCHLORIDE, injections, 20 mg in 2 mL and 50 mg in 5 mL, Apomine® Hospira Pty Ltd	Parkinson disease	Addition to the General Schedule as Authority required listings for the maintenance of Parkinson disease in patients severely disabled by motor fluctuations who do not respond to other therapy. Initiation of therapy would still remain as Section 100 (Highly Specialised Drugs Program) listings.

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New drug application (Major submission)	BOCEPREVIR with PEGINTERFERON ALFA-2B and RIBAVIRIN, pack containing 336 capsules boceprevir 200 mg, 112 capsules ribavirin 200 mg, 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent; pack containing 336 capsules boceprevir 200 mg, 112 capsules ribavirin 200 mg, 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent; pack containing 336 capsules boceprevir 200 mg, 140 capsules ribavirin 200 mg, 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent; pack containing 336 capsules boceprevir 200 mg, 140 capsules ribavirin 200 mg, 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent; pack containing 336 capsules boceprevir 200 mg, 168 capsules ribavirin 200 mg, 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent; pack containing 336 capsules boceprevir 200 mg, 196 capsules ribavirin 200 mg, 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent, Victrelis Pegatron® Combination Therapy Merck Sharp & Dohme (Australia) Pty Limited	Hepatitis C	Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for the treatment of chronic hepatitis C in treatment naïve and treatment experienced patients aged 18 years and older who meet certain criteria.
Re-submission (Minor submission)	BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE, oral pressurised inhalation, 50 micrograms – 3 micrograms per dose, 100 micrograms – 3 micrograms per dose, 200 micrograms-6 micrograms per dose, Symbicort Rapihaler® AstraZeneca Pty Ltd	Asthma and chronic obstructive pulmonary disease	Re-submission of the 200 micrograms – 6 micrograms presentation to list as a Restricted benefit for the same asthma and chronic obstructive pulmonary disease PBS indications as Symbicort Turbuhaler. The 50/3 micrograms and 100/3 micrograms presentations have not previously been considered by the PBAC.

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Change to listing (Minor submission)	CIPROFLOXACIN, eye drops, 3 mg per mL (0.3%), 5 mL, CiloQuin® and Ciloxan® OFLOXACIN, eye drops, 3 mg per mL (0.3%), 5 mL, Ocuflox® Optometrists Association Australia	Eye infection	Change the current Authority Required listing under the Optometrical schedule to remove the current requirement for optometrists to be under the supervision and direction of an ophthalmologist.
Review	EMERGENCY DRUG SUPPLIES LIST (DOCTOR'S BAG) REVIEW	Emergency Drug Supplies	To review which drugs may be appropriate to include in this section, their doses, and maximum quantities.
New drug application (Major submission)	EVEROLIMUS, tablets, 2.5 mg, 5 mg and 10 mg, Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Subependymal giant cell astrocytoma (SEGA)	Authority Required listing for the initial and continuing treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) in a patient who meets certain criteria.
New drug application (Major submission)	EVEROLIMUS, tablets, 5 mg and 10 mg, Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Pancreatic neuroendocrine tumour	Authority Required listing for the initial and continuing treatment of unresectable or metastatic, well or moderately differentiated pancreatic neuroendocrine tumour in a patient who meets certain criteria.
Re-submission (Minor submission)	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), Atozet Composite Pack®	High cholesterol	Authority Required (Streamlined) listing for the treatment, in conjunction with dietary therapy and exercise, of a patient whose cholesterol levels are inadequately controlled with a statin and who meet certain criteria.
Change to listing (Minor submission)	EZETIMIBE, tablet, 10 mg, Ezetrol®; EZETIMIBE with SIMVASTATIN, tablet, 10 mg-10 mg, 10 mg-20 mg, 10 mg-40mg and 10 mg-80mg, Vytorin® Merck Sharp & Dohme (Australia) Pty Ltd	High cholesterol	Requests a change to the existing restriction wording from the requirement to have 3 months therapy at the maximum tolerated dose of a statin prior to initiation of ezetimibe or ezetimibe-simvastatin, to 6 weeks therapy.
New drug application (Major submission)	FAMPRIDINE, modified release tablet, 10 mg, Fampyra® Biogen Idec Australia Pty Ltd	Multiple sclerosis	Authority Required listing for initial and continuing treatment for the symptomatic improvement of walking ability of an ambulatory patient with clinically definite multiple sclerosis who meets certain criteria.

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New drug application (Minor submission)	FOLIC ACID, tablet, 500 micrograms, Foltabs® Petrus Pharmaceuticals Pty Ltd	Folic acid supplement	Unrestricted benefit listing.
Re-submission (Major submission)	GEFITINIB, tablet, 250 mg, Iressa® AstraZeneca Pty Ltd	Lung cancer	Extend the current Authority Required listing to include first line treatment of locally advanced or metastatic non-small cell lung cancer in a patient who meets certain criteria.
New drug application (Minor submission)	GLUCOSE INDICATOR – BLOOD, test strips, 50, DANA Blood Glucose® Managing Diabetes Pty Ltd	Blood glucose monitoring	Unrestricted benefit listing.
Re-submission (Major submission)	IMATINIB, tablets, 100 mg and 400 mg, (as mesylate) Glivec® Novartis Pharmaceuticals Australia Pty Ltd	Gastrointestinal cancer	Change the current Authority required listing in gastrointestinal stromal tumour to allow a maximum duration of treatment of 3 years (currently 12 months).
New drug application (Minor submission)	IMIQUIMOD, cream, 50 mg per g (5%), 2 g multi-use pump, Aldara® iNova Pharmaceuticals (Australia) Pty Ltd	Skin cancer	Listing of a 'pump' presentation for the same superficial basal cell carcinoma PBS indication as the existing single use sachets.
New drug application (Major submission)	INGENOL, gel, 0.15 mg per g (0.015%), 70 mcg ingenol mebutate in 0.47 g single use tubes, 3 Picato® LEO Pharma Pty Ltd	Skin cancer	Authority Required listing for the field treatment of solar keratoses of the face and scalp in patients where topical fluorouracil 5% (5-FU) is clinically inappropriate.
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	Section 100 (Efficient Funding of Chemotherapy) Authority Required (Streamlined) listing for the 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.
Re-submission (Minor submission)	IVABRADINE, tablets, 5 mg and 7.5 mg (as hydrochloride), Coralan® Servier Laboratories (Australia) Pty Ltd	Heart failure	Authority Required benefit for the treatment of symptomatic systolic heart failure in patients meeting certain criteria.

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Change to listing (Major submission)	LACOSAMIDE, tablets, 50 mg, 100 mg, 150 mg and 200 mg, Vimpat® UCB Australia Pty Ltd	Epilepsy	Extend the current Authority Required listing to include an Authority Required (Streamlined) listing for the treatment of partial onset seizures and secondarily generalised seizures, in combination with two or more anti-epileptic drugs, in a patient with refractory epilepsy, aged 16 years or older.
New drug application (Minor submission)	LEVONORGESTREL with ETHINYLOESTRADIOL, tablet, 100 micrograms – 20 micrograms, Femme-Tab ED® AFT Pharmaceuticals Pty Ltd	Oral contraceptive	Unrestricted benefit listing of a combined oral contraceptive with a lower strength oestrogen component (20 micrograms) compared with existing PBS-listed combined oral contraceptives.
Change to listing (Major submission)	MARAVIROC, tablets, 150 mg and 300 mg, Celsentri® GlaxoSmithKline on behalf of ViiV Healthcare	HIV infection	Extend the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include first line treatment, in combination with other antiretroviral agents, of a patient with CCR5-tropic HIV-1 infection, who meets certain criteria.
New vaccine application for inclusion on the National Immunisation Program (Major submission)	MEASLES, MUMPS, RUBELLA and VARICELLA VIRUS VACCINE LIVE, injection, 0.5 mL, ProQuad® CSL Biotherapies (CSL Limited)	Childhood immunisation	Inclusion on the National Immunisation Program (NIP) Schedule for immunisation of children aged 18 months, as an alternative combination vaccine to the currently recommended vaccine, Priorix-Tetra.
New drug application (Major submission)	MILNACIPRAN, capsules, 25 mg, 50 mg and 100 mg (as hydrochloride), Jonica® Pierre Fabre Medicament Australia Pty Ltd	Fibromyalgia	Restricted Benefit listing for the management of an adult patient with fibromyalgia, after failure of standard treatment options, who meets certain criteria.
Re-submission (Minor submission)	NAPROXEN with ESOMEPRAZOLE, tablet, 500 mg – 20 mg (as magnesium trihydrate), Vimovo® AstraZeneca Pty Ltd	Anti-inflammatory	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.

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Change to listing (Minor submission)	NILOTINIB, capsule, 200 mg (as hydrochloride monohydrate), Tasigna® Novartis Pharmaceuticals Australia Pty Ltd	Leukaemia	To allow patients receiving nilotinib 400 mg twice daily in the TIDEL-II clinical trial to access nilotinib 200 mg capsules under the PBS.
Change to listing (Minor submission)	OLMESARTAN with AMLODIPINE, tablet, 20 mg – 5 mg, 40 mg – 5 mg and 40 mg – 10 mg (as besylate), Sevikar®; OLMESARTAN with HYDROCHLOROTHIAZIDE, tablet, 20 mg – 12.5 mg, 40 mg – 12.5 mg and 40 mg – 25 mg, Olmetec® Plus Merck Sharp & Dohme (Australia) Pty Ltd	High blood pressure	Change the wording of the existing restriction to 'Treatment of hypertension. Treatment should not be initiated with combination therapy'
Change to listing (Major submission)	PAZOPANIB, tablets, 200 mg and 400 mg (as hydrochloride), Votrient® GlaxoSmithKline Pty Ltd	Cancer in soft tissue	Extension to the recommended Authority Required listing to include the initial and continuing treatment of advanced (unresectable and/or metastatic) soft tissue sarcoma in a patient who meets certain criteria.
Change to listing (Minor submission)	POSACONAZOLE, oral suspension, 40 mg per mL, Noxafil® Merck Sharp & Dohme (Australia) Pty Ltd	Antifungal	1) Change the current Authority Required PBS listing to an Authority Required (Streamlined) listing 2) Remove the restriction wording pertaining to the cause of neutropenia.
Re-submission (Minor submission)	PRUCALOPRIDE, tablets, 1 mg and 2 mg (as succinate), Resotrans® Janssen-Cilag Pty Ltd	Constipation	Restricted Benefit listing for the treatment of chronic functional constipation in adults meeting certain criteria.
Change to listing (Major submission)	RANIBIZUMAB, solution for intravitreal injection, 2.3 mg in 0.23 mL, Lucentis® Novartis Pharmaceuticals Australia Pty Ltd	Vision loss	Extend the current Authority Required listing to include the initial and continuing treatment by an ophthalmologist, of visual impairment due to macular oedema secondary to retinal vein occlusion.

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New drug application (Minor submission)	RIBAVIRIN and PEGINTERFERON ALFA-2a, pack containing 168 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 135 micrograms, pack containing 112 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 180 micrograms, pack containing 140 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 180 micrograms, pack containing 168 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 180 micrograms , Pegasys RBV® Roche Products Pty Ltd	Chronic hepatitis C	Authority Required listing of packs containing ribavirin tablets and peginterferon alfa-2a pre-filled pens for the same chronic hepatitis C indications as for the current Pegasys RBV combination packs that contain ribavirin tablets and peginterferon alfa-2a pre-filled syringes.
Re-submission (Minor submission)	RIFAXIMIN, tablet, 550 mg, Xifaxan® Norgine Pty Ltd	Liver disease	Authority Required listing for the prevention of hepatic encephalopathy in adult patients meeting certain criteria.
Re-submission (Major submission)	RIVAROXABAN, tablets, 15 mg and 20 mg, Xarelto® Bayer Australia Ltd	Anti-thrombotic drug	Authority Required (Streamlined) listing for the prevention of stroke or systemic embolism in an adult patient with non-valvular atrial fibrillation who meets certain criteria.
Re-submission (Minor submission)	SAPROPTERIN, soluble tablet, 100 mg (as dihydrochloride), Kuvan® Merck Serono Australia Pty Ltd	Hyperphenylalaninaemia	Inclusion on the Life Saving Drugs Program for the treatment of hyperphenylalaninaemia in patients demonstrated to have tetrahydrobiopterin deficiency.
New drug application (Major submission)	SITAGLIPTIN with SIMVASTATIN, tablets, 100 mg–10 mg, 100 mg–20 mg and 100 mg–40 mg, Juvicor® Merck Sharp & Dohme (Australia) Pty Ltd	Type 2 diabetes and high cholesterol levels	Authority Required (Streamlined) listing for use in patients with Type 2 diabetes who are currently receiving treatment with simvastatin and who satisfy the criteria for prescribing DPP-4 inhibitors.
Re-submission (Major submission)	SORAFENIB, tablet, 200 mg (as tosylate), Nexavar® Bayer Australia Ltd	Renal cancer	Extend the current Authority Required listing to include the initial and continuing treatment of Stage IV clear cell renal carcinoma in a patient who has failed therapy with first line treatment and who meets certain criteria.

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Re-submission (Minor submission)	STRONTIUM RANELATE, sachet containing granules for oral suspension, 2g, Protos® Servier Laboratories (Australia) Pty Ltd	Osteoporosis	To change the basis of the PBAC's July 2012 recommendation to extend strontium's Authority Required (Streamlined) listing to include use for osteoporosis in males aged 70 years and over with a BMD T-score of -3.0.
Re-submission (Minor submission)	TAPENTADOL, tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg (as hydrochloride) (sustained release), Palexia SR® CSL Biotherapies (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)	TERIFLUNOMIDE, tablet, 14 mg, Aubagio® Genzyme (Sanofi-Aventis Australia Pty Ltd)	Multiple sclerosis	Authority Required listing for the initial and continuing treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory patients who meet certain criteria.
New drug application (Minor submission)	THIAMINE HYDROCHLORIDE, tablet, 100 mg, Betavit® Petrus Pharmaceuticals Pty Ltd	Thiamine (vitamin B1) supplement	Authority Required (STREAMLINED) listing for the prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person.
Re-submission (Major submission)	TRASTUZUMAB, powder for I.V. infusion, 60 mg and 150 mg, Herceptin® Roche Products Pty Ltd	Stomach and gastrointestinal cancer	Extend the current Section 100 (Efficient Funding of Chemotherapy) Authority Required listing to include the treatment of HER2 positive, advanced (equivalent stage III or IV) adenocarcinoma of the stomach or gastro-oesophageal junction, in patients who have not received prior treatment for advanced disease, in combination with cisplatin and either capecitabine or 5-fluorouracil, with a WHO performance status of 2 or less and who does not have progressive disease.
Change to listing (Minor submission)	TRIGLYCERIDES, MEDIUM CHAIN, oil, 500 mL, MCT Oil® TRIGLYCERIDES, MEDIUM CHAIN, emulsion, 250 mL, Liquigen® Nutricia Australia Pty Ltd	Medicinal food	Notification of minor formulation changes to MCT Oil and Liquigen and of a packaging change to Liquigen.

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Change to listing (Major submission)	VARENICLINE, tablets, 0.5 mg and 1 mg (as tartrate) (titration pack), tablet, 1 mg (as tartrate), Champix® Pfizer Australia Pty Ltd	Smoking cessation	Amendment of the NOTE to permit a further course of varenicline treatment in patients who did not cease smoking after a course of varenicline or bupropion treatment, provided 6 months have elapsed between treatments.
Change to listing (Major submission)	VINORELBINE, capsules, 20 mg and 30 mg (as tartrate), Navelbine® Pierre Fabre Medicament Australia Pty Ltd	Breast cancer	Extend the current Authority Required listing to include an Authority Required (Streamlined) listing for the treatment of advanced breast cancer after failure of standard prior therapy, as a single agent or in combination.
Change to listing (Major submission)	ZOLEDRONIC ACID, solution for I.V. infusion, 5 mg (as monohydrate) in 100 mL, Aclasta® Novartis Pharmaceuticals Australia Pty Ltd	Osteoporosis	Extend the current Authority Required (Streamlined) listing to include the treatment of patients aged 70 years of age or older, with a Bone Mineral Density (BMD) T-score of -2.5 or less.