PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2013 PBAC MEETING

Closing date for consumer comments 12 June 2013

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*
New Listing (Major submission)	AFATINIB, tablets, 20 mg, 30 mg, 40 mg and 50 mg, Giotrif®/Tomtovok® Boehringer Ingelheim Pty Ltd	Lung cancer	Authority required listing for locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer as first line therapy in a patient with activating mutation(s) of the EGFR gene.
New Listing (Major submission)	AFATINIB, tablets, 20 mg, 30 mg, 40 mg and 50 mg, Giotrif®/Tomtovok®: Boehringer Ingelheim Pty Ltd	Lung cancer	Authority required listing for locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer as second or third line therapy.
Change to Listing (Major submission)	AFLIBERCEPT, solution for intravitreal injection, 40 mg per mL, Eylea® Bayer Australia Limited	Vision loss	Extend the current Authority required listing to include sole subsidised treatment of patients with macular oedema caused by central retinal vein occlusion (CRVO).
New Listing (Major submission)	AFLIBERCEPT, solution for I.V. administration, 100 mg per 4 mL and 200 mg per 8 mL, Zaltrap®: Sanofi-Aventis Australia Pty Ltd	Bowel cancer	Authority Required (STREAMLINED) listing for treatment, in combination with an irinotecan-fluoropyrimidine-based chemotherapy, of a patient with previous treatment with an oxaliplatin-based chemotherapy regimen for metastatic colorectal cancer with a WHO performance status of 0 or 1.
New Listing (Major submission)	ALOGLIPTIN, tablets, 6.25 mg, 12.5 mg and 25 mg, Nesina® Takeda Pharmaceuticals Australia Pty Ltd	Type 2 diabetes	Authority required (STREAMLINED) listing for dual oral combination therapy with metformin or a sulfonylurea in type 2 diabetes.

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New Listing (Minor submission)	AMINO ACID FORMULA- SYNTHETIC, oral liquid, powder for, 400 g, Alfamino® Nestlé Australia Ltd	Medicinal food	Requests an Authority Required listing for infants and children with cow's milk allergy.
New Listing (Minor submission)	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALALINE, oral liquid, 60 x 62.5 mL cans, PKU Lophlex LQ® 10 Nutricia Australia Pty Ltd	Medicinal food	Requests a Restricted benefit listing for two additional flavour variants to the current PKU Lophlex LQ 10 range.
New Listing (Minor submission)	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE, oral, semi-solid, carton of 36 x 109 g PKU Lophlex Sensation 20® Nutricia Australia Pty Ltd	Medicinal food	Restricted benefit listing of a phenylalanine-free protein substitute for the management of Phenylketonuria (PKU).
Change to Listing (Minor submission)	AMINO ACID SYNTHETIC FORMULA, oral liquid, powder for, 400 g, NEOCATE® ADVANCE VANILLA with Prebiotics Nutricia Australia Pty Ltd	Medicinal food	To highlight minor changes to the formulation and confirm that the product remains compliant with the FSANZ Standard for Foods for Special Medical Purposes 2.9.5.
Re-submission (Major submission)	BOTULINUM TOXIN, 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.
New Listing (Major submission)	BUDESONIDE, foam enema, 2 mg per application, Budenofalk® Orphan Australia Pty Ltd	Ulcerative colitis	Unrestricted benefit for treatment of active rectal and rectosigmoid disease in ulcerative colitis.
Re-submission (Major submission)	BUDESONIDE WITH EFORMOTEROL FUMARATE DIHYDRATE, oral pressurised inhalation, 50 mcg-3 mcg, 100 mcg-3 mcg, 200 mcg-6 mcg per dose, Symbicort Rapihaler® AstraZeneca Pty Ltd	Asthma	Re-submission requesting a Restricted benefit listing for maintenance and reliever therapy in patients with frequent asthma symptoms.

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New Listing (Major submission)	CANAGLIFLOZIN, tablets, 100 mg and 300 mg, Invokana® Janssen-Cilag Pty Ltd	Type 2 diabetes	Authority required listing for patients with type 2 diabetes as dual oral combination therapy with metformin or a sulfonylurea.
New Listing (Minor submission)	CARBOMER 980, eye gel, 2 mg per mL (0.2%), 10 g tube, Optifresh Eye Gel® Petrus Pharmaceuticals	Ocular lubricant	Restricted benefit listing in the general and optometrical schedules for severe dry eye syndrome, including Sjogren's syndrome.
New Listing (Minor submission)	CARMELLOSE SODIUM, eye drops, 5 mg per mL (0.5%), 0.4 ml x 30 unit doses, Optifresh Tears Eye Drops® CARMELLOSE SODIUM, eye drops, 10 mg per mL (1%), 0.4 ml x 30 unit doses, Optifresh Plus® Petrus Pharmaceuticals	Ocular lubricant	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
New Listing (Major submission)	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM, injection, 0.9 mg per vial, Xiaflex® Actelion Pharmaceuticals Australia Pty Ltd	Dupuytren's contracture	Authority Required listing for treatment of Dupuytren's contracture for patients who are unable to simultaneously place the affected finger and palm flat on a table due to a Dupuytren's contracture with a palpable cord.
Re-submission (Minor submission)	DABRAFENIB, capsules, 50 mg and 75 mg, Tafinlar® GlaxoSmithKline Australia Pty Ltd	Melanoma	To provide further information to the Committee to allow the PBAC to make a recommendation on the March 2013 submission seeking an Authority required listing for treatment of patients with BRAF V600 mutation positive advanced (unresectable stage III) or metastatic (stage IV) melanoma.
Re-submission (Major submission)	DAPAGLIFLOZIN, tablet, 10 mg, Forxiga® Bristol-Myers Squibb Australia Pty Ltd	Type 2 diabetes	Authority required listing for patients with type 2 diabetes as dual oral combination therapy with metformin or a sulfonylurea.
New Listing (Minor submission)	DARUNAVIR, tablet, 800 mg, Prezista® Janssen-Cilag Pty Ltd	Human immunodeficiency virus (HIV) infection	Request to replace the currently PBS listed 400 mg tablet with an 800 mg tablet for patients with HIV infection.

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Change to Listing (Major submission)	DENOSUMAB, injection, 60 mg per mL, Prolia® Amgen Australia Pty Ltd	Osteoporosis	Requests extension of Authority required (STREAMLINED) listing to include males with osteoporosis who meet the same eligibility criteria that currently apply to women (i.e. sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a T-score of -2.5 or less).
New Listing (Major submission)	DIMETHYL FUMARATE, capsules, 120 mg and 240 mg, Tecfidera® Biogen Idec Australia Pty Ltd	Multiple sclerosis	Authority required listing as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient who meets certain criteria.
Change to Listing (Major submission)	ELTROMBOPAG OLAMINE, tablets, 25 mg, 50 mg, 75 mg and 100 mg, Revolade® GlaxoSmithKline Australia Pty Ltd	Decreased platelet count	Extend the current Section 100 listing to include treatment of thrombocytopenia in patient with documented chronic hepatitis C virus.
Re-submission (Major submission)	ERLOTINIB, tablets, 25 mg, 100 mg and 150 mg, Tarceva® Roche Products Pty Limited	Lung cancer	Extend the current Authority required listing to include treatment, as monotherapy of locally advanced (stage IIIB) or metastatic (stage IV) non-squamous or not otherwise specified (NOS) non-small cell lung cancer in patients where there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material.
Re-submission (Minor submission)	EVEROLIMUS, tablets, 5 mg and 10 mg, Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Breast cancer	Re-submission for an Authority required listing for treatment with everolimus in combination with exemestane, of post-menopausal women with hormone receptor (HR) positive, HER2 negative advanced breast cancer after failure of letrozole or anastrozole.

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Re-submission (Minor submission)	EXENATIDE, powder for injection, 2 mg vial with diluent, Bydureon® Bristol-Myers Squibb Australia Pty Ltd	Type 2 diabetes	Authority required listing for the treatment of type 2 diabetes as i) Dual combination therapy with metformin or a sulfonylurea, and ii) Triple combination therapy with metformin and a sulfonylurea for patients who have not yet achieved adequate glycaemic control.
Re-submission (Major submission)	EZETIMIBE WITH ATORVASTATIN, tablets, 10 mg-10 mg, 20 mg-10 mg, 40 mg-10 mg and 80 mg-10 mg, Atozet® co-pack Merck Sharp & Dohme (Australia) Pty Limited	High cholesterol	Re-submission for an Authority required (STREAMLINED) listing for hypercholesterolaemia in patients meeting certain criteria.
New Listing (Major submission)	FENTANYL, nasal spray, 100 mcg and 400 mcg, PecFent® AstraZeneca Pty Ltd	Analgesic	Restricted benefit listing for the management of breakthrough pain in adults with cancer receiving maintenance opioid therapy for chronic pain.
New Listing (Major submission)	FLUTICASONE WITH EFORMOTEROL, metered dose inhalers, 50 mcg-5 mcg, 125 mcg-5 mcg and 250 mcg-10 mcg, Flutiform® Mundipharma Pty Ltd	Asthma	Restricted benefit listing for patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and/or optimal doses of inhaled corticosteroids requiring treatment with a combination of and inhaled corticosteroid and a long acting beta-2 agonist.
Re-submission (Major submission)	GEFITINIB, tablet, 250 mg, Iressa® AstraZeneca Pty Ltd	Lung cancer	Extend the current Authority required listing to include initial and continuing treatment of locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer in patients where there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material.
New Listing (Minor submission)	GLUCOSE INDICATOR – BLOOD, test strips, 2 x 50 per pack, CONTOUR® NEXT, Blood Glucose Test Strips Medtronic Australasia Pty Ltd	Blood glucose monitoring	Requests an unrestricted benefit listing and also a Restricted benefit listing for patients receiving treatment under a GP management plan or team care arrangements.

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Change to Listing (Minor submission)	HIGH FAT FORMULA with VITAMINS, MINERALS AND TRACE ELEMENTS and LOW in PROTEIN and CARBOHYDRATE, oral liquid, powder for: 300g, KETOCAL® 4:1 Nutricia Australia Pty Ltd	Medicinal food	To highlight minor changes to the formulation and confirm that the product remains compliant with the FSANZ Standard for Foods for Special Medical Purposes 2.9.5.
New Listing (Major submission)	IVACAFTOR, tablet, 150 mg, Kalydeco®: Vertex Pharmaceuticals	Cystic fibrosis	Requests Section 100 (Highly Specialised Drugs Program) listing or inclusion on the Life Saving Drugs Program (LSDP) for treatment of cystic fibrosis in patients aged six years and older who have a G551D mutation in the CFTR gene.
Change to Listing (Minor submission)	IVERMECTIN, tablet, 3 mg, Stromectol® Merck, Sharp & Dohme (Australia) Pty Limited	Roundworm infestation	Requests amendment of the current Authority required (STREAMLINED) listing for an increased maximum quantity and number of repeats.
New Listing (Major submission)	LEVONORGESTREL, intrauterine system, 13.5 mg, Jaydess® Bayer Australia Limited	Contraception	Restricted benefit listing for contraception.
Re-submission (Major submission)	LINEZOLID, tablet 600 mg, oral liquid 20 mg per mL, injection 600 mg per 300 mL, Zyvox® Pfizer Australia Pty Ltd	Antibiotic	Re-submission for an Authority Required listing for treatment of microbiologically proven, multi-resistant methicillin-resistant *Staphylococcus* species (MRSS) infection in patients where no other antimicrobial agents can be used or treatment of microbiologically proven vancomycin resistant enterococci (VRE) infection.
New Listing (Major submission)	LISDEXAMFETAMINE DIMESILATE, capsules, 30 mg, 50 mg, and 70 mg, Vyvanse® Shire Australia Pty Ltd	Attention Deficit Hyperactivity Disorder (ADHD)	Authority required listing for treatment of ADHD in a patient diagnosed between the ages of 6 and 18 years who requires continuous coverage over 13 hours.
New Listing (Minor submission)	MILK POWDER LACTOSE FREE FORMULA PREDIGESTED, oral liquid, powder for, 900g, Karicare Aptamil Gold De-Lact® Nutricia Australia Pty Ltd	Medicinal food	Requests listing of a new formula to replace the currently listed Authority required product.

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Re-submission (Minor submission)	MOMETASONE FUROATE, hydrogel, 0.1% (1 mg per g), 15g, Zatamil® Ego Pharmaceuticals Pty Ltd	Skin lesions	Resubmission for a Restricted benefit listing for treatment of corticosteroid-responsive dermatoses.
New Listing (Major submission)	MOMETASONE WITH EFORMOTEROL, metered dose inhaler, 50 mcg-5 mcg, 100 mcg-5 mcg and 200 mcg-5 mcg, Zenhale® Merck Sharp & Dohme (Australia) Pty Limited	Asthma	Restricted benefit listing for patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate and mometasone furoate.
New Listing (Major submission)	NABIXIMOLS, oromucosal spray, 27 mg per mL tetrahydrocannabinol and 25 mg per mL cannabidiol, 3x10 mL, Sativex® Novartis Pharmaceuticals Australia Pty Ltd	Multiple Sclerosis	Authority required listing for management of severe spasticity due to multiple sclerosis in adult patients who are intolerant to anti-spasticity medication and/or have not adequately responded to anti-spasticity medication.
Review	NAPROXEN with ESOMEPRAZOLE, tablet, 500 mg – 20 mg (as magnesium trihydrate), Vimovo® AstraZeneca Pty Ltd	Symptomatic treatment of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis	Report on the Independent Review for naproxen with esomeprazole for the symptomatic treatment of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis.
Change to Listing (Minor submission)	OLANZAPINE PAMOATE MONOHYDRATE, injection, 210 mg, 300 mg and 405 mg, Zyprexa Ralprevv® Eli Lilly Australia Pty Ltd	Bipolar disorder	Request to update the CAUTION note linked to this restriction to reflect the updated TGA approved Product Information.
New Listing (Major submission)	OLMESARTAN WITH AMLODIPINE AND HYDROCHLOROTHIAZIDE, tablets, 20 mg-5 mg-12.5 mg, 40 mg-5 mg-12.5 mg, 40 mg-5 mg-25 mg, 40 mg-10 mg-12.5 mg and 40 mg-10 mg-25 mg, Sevikar HCT® Merck Sharp & Dohme (Australia) Pty Limited	High blood pressure	Restricted benefit listing for the treatment of hypertension where the condition is not adequately controlled with two of either an angiotensin II receptor antagonist, calcium channel blocker or diuretic.

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Re-submission (Major submission)	PAZOPANIB, tablet, 200 mg and 400 mg, Votrient® GlaxoSmithKline Australia Pty Ltd	Cancer in soft tissue	Re-submission to extend the current Authority required listing to include advanced (unresectable and/or metastatic) soft tissue sarcoma.
New Listing (Minor submission)	POTASSIUM IODATE, tablet, 253 mcg equivalent to 150 mcg iodine, NeuroTabs® AFT Pharmaceuticals Pty Ltd	Iodine deficiency	Restricted benefit listing for iodine supplementation for pregnant and lactating women at risk of developing iodine deficiency
Re-submission (Major submission)	QUETIAPINE, tablets, 50 mg, 150 mg, 200 mg and 300 mg, Seroquel XR® AstraZeneca Pty Ltd	Depression	Re-submission to extend the current Authority required (STREAMLINED) listing to include treatment of recurrent major depressive disorder in combination with current antidepressant therapy in patients treated by a psychiatrist, or a GP in consultation with a psychiatrist, who have had inadequate response to two prior antidepressant therapies.
New Listing (Major submission)	RUXOLITINIB, tablet, 5 mg, 15 mg and 20 mg, Jakavi® Novartis Pharmaceuticals Australia Pty Ltd	Bone marrow disorder	Authority required listing for treatment of disease-related symptoms in patients with intermediate or high-risk primary (idiopathic) myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.
New Listing (Major submission)	STRONTIUM RANELATE WITH COLECALCIFEROL, sachet containing strontium ranelate 2 g – colecalciferol 25 mcg, 28, Protos D® Servier Laboratories (Australia) Pty Ltd	Osteoporosis	Authority required (STREAMLINED) listing as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a bone mineral density (BMD) T-score of -3.0 or less, and, established osteoporosis where the patient has had a fracture due to minimal trauma.
Change to Listing (Minor submission)	TERBUTALINE SULPHATE, turbuhaler, 500 µg per dose, 100 dose, Bricanyl Turbuhaler® AstraZeneca Pty Ltd	Asthma	Request to replace existing 200-dose turbuhaler with a 100-dose turbuhaler.

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Re-submission (Major submission)	TERIFLUNOMIDE, tablet, 14 mg, Aubagio® Genzyme (Sanofi-Aventis Pty Ltd)	Multiple sclerosis.	Re-submission for an Authority required listing for the initial and continuing treatment of Relapsing-Remitting Multiple Sclerosis in ambulatory patients who meet certain criteria.
Change to Listing (Major submission)	TOCILIZUMAB, injection, 80 mg per 4 ml, 200 mg per 10 mL and 400 mg per 20 mL, Actemra®: Roche Products Pty Limited	Rheumatoid arthritis	Authority required listing for severe rheumatoid arthritis where a patient has had an inadequate response to disease modifying anti rheumatic drugs (DMARDs), (including methotrexate), and/or where a patient cannot tolerate 7.5 mg of methotrexate weekly.
New Listing (Major submission)	TRASTUZUMAB EMTANSINE, powder for I.V. infusion, 100 mg and 160 mg, Kadcyla® Roche Products Pty Limited	Breast cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for treatment of a patient with HER2-positive unresectable locally advanced or metastatic breast cancer who has received prior therapy with trastuzumab (Herceptin®) and a taxane and whose disease has progressed despite treatment with trastuzumab for metastatic disease or within 6 months of completing adjuvant therapy.
Change to Listing (Major submission)	VILDAGLIPTIN, tablet, 50 mg, Galvus®: Novartis Pharmaceuticals Australia Pty Ltd	Type 2 diabetes	Authority required (STREAMLINED) listing for patients with type 2 diabetes in triple combination therapy with metformin and a sulfonylurea.
Change to Listing (Major submission)	VILDAGLIPTIN WITH METFORMIN, tablets, 50 mg-500 mg, 500 mg-850 mg and 50 mg-1000 mg, Galvumet® Novartis Pharmaceuticals Australia Pty Ltd	Type 2 diabetes	Authority required (STREAMLINED) listing for patients with type 2 diabetes in combination with a sulfonylurea (i.e. triple combination therapy).
Change to Listing (Minor submission)	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE, powder, 400g, RenaStart® Vitaflo Australia Pty Ltd	Medicinal food	Notification of a pack size change and minor amendments to the kilojoule, linoleic acid and alpha linolenic acid contents to Renastart.