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

Closing date for consumer comments 9 October 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.

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

Closing date for consumer comments 9 October 2013

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*
Change to Listing (Major submission)	ADALIMUMAB, 40 microgram/0.8 mL injection, 2 x 0.8 mL cartridges and 6 x 0.8 mL cartridges; 40 mg/0.8 mL injection, 2 x 0.8 mL syringes and 6 x 0.8 mL syringes Humira® AbbVie Pty Ltd	Ulcerative colitis	To request Authority Required listing for the treatment of adult patients with moderately to severely active ulcerative colitis.
New Listing (Major submission)	ALOGLIPTIN WITH METFORMIN, alogliptin 12.5mg + metformin 500mg, alogliptin 12.5mg + metformin 850mg, alogliptin 12.5mg + metformin 1000mg, tablet Nesina Met® Takeda Pharmaceuticals Australia Pty Ltd	Type 2 Diabetes	To request an Authority Required (STREAMLINED) listing for the treatment of type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor, a thiazolidinedione or a glucagon-like peptide-1, despite treatment with metformin and where a combination of metformin and sulfonylurea is contraindicated or not tolerated.
Change to Listing (Minor submission)	AMINO ACID FORMULA WITHOUT PHENYLALANINE, 1 g tablet, 75 Phlexy-10® Nutricia Australia Pty Ltd	Medicinal food	To advise the PBAC and Nutritional Products Working Party of a minor change to the nutritional information of Phlexy-10 tablets.

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

Closing date for consumer comments 9 October 2013

Change to Listing (Major submission)	ANTIRETROVIRAL THERAPY Australasian Society for HIV Medicine (ASHM), National Association of People with HIV Australia (NAPWHA), Australian Federation of AIDS Organisations (AFAO)	Human immunodeficiency virus (HIV) infection	To request the removal of the CD4+ cell count restriction for initiation of first line anti-retroviral therapy (ART) in asymptomatic, ART naïve HIV positive patients.
New Listing (Minor submission)	ARGININE WITH CARBOHYDRATE, containing 5000 mg arginine oral liquid: powder for, 30 x 7.6 g sachets Arginine 5000® Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted benefit listing for urea cycle disorders for an additional strength of arginine with carbohydrate.
New Listing (Major submission)	AXITINIB, 1 mg and 5 mg, tablet Inlyta® Pfizer Australia Pty Ltd	Renal Cell Carcinoma (RCC)	To request Authority Required listing for the treatment of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient who meets certain criteria.
Re-submission (Minor submission)	BETAMETHASONE DIPROPIONATE + CALCIPOTRIOL, betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g Daivobet® Leo Pharma Pty Ltd	Psoriasis of the scalp	To request a Restricted benefit listing for a larger size (60g) for treatment of chronic stable plaque type psoriasis vulgaris of the scalp in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy.
Change to Listing (Major submission)	BEVACIZUMAB, 100 mg/4 mL and 400 mg/16 mL, injection, vial Avastin® Roche Products Pty Limited	Advanced epithelial ovarian, fallopian tube or primary peritoneal cancer	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (+/- STREAMLINED) listings for the treatment, in combination with paclitaxel and carboplatin, of a patient with previously untreated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who is at high risk of disease recurrence.

Closing date for consumer comments 9 October 2013

New Listing (Minor submission)	BIMATOPROST, 0.03% eye drops, preservative free, 30 x 0.4 mL unit doses Lumigan® PF Allergan Pty Ltd	Glaucoma	To request an Unrestricted benefit listing within the General Schedule and Optometrist Schedule of a preservative free, unit dose presentation of bimatoprost eye drops.
Change to Listing (Major submission)	BOTULINUM TOXIN TYPE A, 100 units, injection, 1 x 100 units vial Botox® Allergan Australia Pty Ltd	Urinary Incontinence	To request a Section 100 (Botulinum Toxin Program) Authority Required listing for the treatment of urinary incontinence due to idiopathic overactive bladder, in a patient who meets certain criteria.
New Listing (Minor submission)	CARBOHYDRATE, FAT, VITAMINS, MINERALS, TRACE ELEMENTS, LONG CHAIN POLYUNSATURATES (LCPs) ARACHIDONIC ACID (AA) AND DOCOSAHEXANOIC ACID (DHA), PROTEIN FREE FORMULA, oral liquid: powder for 21.5 g x 30 sachets, BaseCal 100® oral liquid: powder for 43 g x 30 sachets, BaseCal 200® Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted benefit listing for patients with proven inborn errors of protein metabolism who are unable to meet their requirements with permitted food and formulae.
Re-submission (Minor submission)	CARBOHYDRATE WITH DOCOSAHEXANOIC ACID, 200 mg, oral liquid: powder for, 4 g x 30 sachets DocOmega® Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted benefit listing for patients with peroxismal biogenesis disorders.

Closing date for consumer comments 9 October 2013

Re-submission (Minor submission)	CARBOHYDRATE WITH DOCOSAHEXANOIC ACID AND ARACHIDONIC ACID, carbohydrate with docosahexanoic acid 100 mg and arachidonic acid 200 mg, oral liquid: powder for, 4 g x 30 sachets KeyOmega® Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted benefit listing for patients with peroxisomal biogenesis disorders.
Re-submission (Major submission)	CETUXIMAB, 100 mg/20 mL and 500 mg/100 mL, injection, vial Erbitux® Merck Serono Australia Pty Ltd	Metastatic colorectal cancer.	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment, in combination with 1st line chemotherapy, of a patient with previously untreated KRAS wild-type metastatic colorectal cancer.
Review (Major submission)	CINACALCET, 30mg, 60mg and 90mg, tablet Senisipar® Amgen Australia Pty Ltd	Secondary hyperparathyroidism in patients with end stage renal disease	To provide the results of the EVOLVE trial and consider the impact of the results on the cost-effectiveness of cinacalcet in the treatment of secondary hyperparathyroidism in patients with end stage renal disease on dialysis and to update the clinical management algorithm based on Australian clinical practice.
New Listing (Major submission)	CLOBETASOL PROPIONATE, 500 microgram per mL shampoo for topical application, 125 mL Clobex® Galderma Australia Pty Ltd	Moderate to severe scalp psoriasis	To request a Restricted benefit listing for the treatment of adults with moderate to severe scalp psoriasis who are not adequately controlled with either a vitamin D analogue or potent corticosteroid mono-therapy.
New Listing (Major submission)	CRIZOTINIB, 200 mg and 250 mg, capsule Xalkori® Pfizer Australia Pty Ltd	Non-small cell lung cancer (NSCLC)	To request Authority Required listing for treatment of a patient with Anaplastic Lymphoma Kinase (ALK) positive non-small cell lung cancer (NSCLC) who has disease progression following at least one platinum-based chemotherapy.

Closing date for consumer comments 9 October 2013

Change to Listing (Major submission)	DENOSUMAB, 120 mg/1.7 mL, injection, vial Xgeva® Amgen Australia Pty Ltd	Giant cell tumour of bone	To request an Authority Required (STREAMLINED) listing for the treatment of giant cell tumour of bone in adult and skeletally mature adolescent patients.
New Listing (Major submission)	DOLUTEGRAVIR, 50 mg, tablet Tivicay® ViiV Healthcare Pty Ltd	Human immunodeficiency virus (HIV) infection	To request Section 100 (Highly Specialised Drugs Program) Authority Required (+/-STREAMLINED) listing for the treatment of HIV infection in combination with other anti-retrovirals, in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease.
Change to Listing (Minor submission)	DOXYCYCLINE, doxycycline 100 mg capsule, modified release, 7 capsules doxycycline 100 mg capsule, modified release, 21 capsules doxycycline 50 mg capsule, modified release, 25 capsules Mayne Pharma Doxycycline® / Doryx® Mayne Pharma International Pty Ltd	Bacterial infection	To request the inclusion of a 'Note' on the PBS listings for doxycycline tablets and capsules stating that doxycycline tablet and capsule forms are equivalent for the purposes of substitution.
Re-submission (Major submission)	ERIBULIN MESILATE, 1 mg/2 mL, injection, vial Halaven® Eisai Australia Pty Ltd	Breast cancer	Resubmission to request Section 100 (Efficient Funding of Chemotherapy) Authority Required (+/-STREAMLINED) listings for the treatment of a patient with locally advanced or metastatic breast cancer who has progressed after a least two chemotherapeutic regimens for advanced disease.

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

Closing date for consumer comments 9 October 2013

New Listing (Minor submission)	ESOMEPRAZOLE MAGNESIUM, 20mg and 40mg modified release capsules Noxicid® Alphapharm Pty Limited	Acid related disorders	To request listing of a new salt and form of esomeprazole (esomeprazole magnesium capsules) under the same conditions as the currently listed esomeprazole magnesium trihydrate tablets (Nexium®) with inclusion of a brand equivalence indicator between the two forms.
Re-submission (Major submission)	EXENATIDE, 2 mg, power for injection, vial Bydureon® Bristol-Myers Squibb Australia Pty Ltd	Type 2 diabetes	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of Type 2 diabetes as: 1) Dual combination therapy with metformin or a sulfonylurea; and 2) Triple combination therapy with metformin and a sulfonylurea; in a patient who meets certain criteria.
New Listing (Major submission)	EZETIMIBE AND ROSUVASTATIN, ezetimibe 10 mg + rosuvastatin 5 mg; ezetimibe 10 mg + rosuvastatin 10 mg; ezetimibe 10 mg + rosuvastatin 20 mg; ezetimibe 10 mg + rosuvastatin 40 mg, tablet Rosuzet® Composite Pack Merck Sharp and Dohme Australia Pty Ltd	High cholesterol	To request an Authority Required (STREAMLINED) listing for the treatment of hypercholesterolemia, in a patient who meets certain criteria.
Re-submission (Major submission)	FERRIC CARBOXYMALTOSE, 500 mg/10 mL, injection, vial Ferinject® Vifor Pharma Pty Ltd	Iron deficiency anaemia	Resubmission to request PBS listing as an unrestricted benefit for the treatment of iron deficiency anaemia.

Closing date for consumer comments 9 October 2013

New Listing (Minor submission)	GLUCOSE INDICATOR BLOOD Glucose indicator blood strip: diagnostic, 100 diagnostic strips, (with 100 lancets per pack) GoodLife Blood Glucose Test Strip® JNS Biomedical Pty Ltd	Diabetes	Request to list a new form of blood glucose test strips.
New Listing (Major submission)	GLYCOPYRRONIUM BROMIDE, 50 microgram, powder for inhalation Seebri® Breezhaler® Novartis Pharmaceuticals Australia Pty Ltd	Chronic Obstructive Pulmonary Disease (COPD).	To request a Restricted benefit listing for the maintenance treatment of chronic obstructive pulmonary disease (COPD).
Change to listing (Minor submission)	HOMATROPINE HYDROBROMIDE, 2% eye drops, 15 mL Isopto Homatropine® Optometrists Association Australia	Anterior uveitis	Request for homatropine to be included on the optometric section of the PBS under the same conditions that it is currently listed for prescribing by medical practitioners and nurse practitioners.
Re-submission (Major submission)	INFLIXIMAB, 100 mg, injection, vial Remicade® Janssen-Cilag Pty Ltd	Ulcerative Colitis	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of acute, severe ulcerative colitis, not responding to IV corticosteroids, in a patient aged 6 years or older who meets certain criteria.
Re-submission (Major submission)	INGENOL MEBUTATE, Gel, 0.15mg per g (0.015%), 3 x0.47g Picato® LEO Pharma Pty Ltd	Skin cancer	Resubmission to request listing as Restricted benefit for field therapy for the treatment of solar keratoses of the face and scalp in patients who have previously diagnosed squamous cell carcinoma.

Closing date for consumer comments 9 October 2013

New listing (Minor submission)	METFORMIN HYDROCHLORIDE, 750 mg tablet, modified release, 60 tablets Diabex XR® Alphapharm Pty Ltd	Diabetes	Requests to list an additional strength of metformin modified release tablet as an Unrestricted benefit.
New Listing (Major submission)	METFORMIN XR AND SAXAGLIPTIN, metformin XR 500 mg + saxagliptin 5 mg; metformin XR 1000 mg + saxagliptin 5 mg and metformin XR 1000 mg + saxagliptin 2.5 mg, tablet, modified release Kombiglyze XR® Bristol Myers Squibb Australia Pty Ltd	Type 2 diabetes	To request an Authority Required (STREAMLINED) listing for the treatment of type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor, a thiazolidinedione or a glucagon-like peptide-1, despite treatment with metformin and where a combination of metformin and sulfonylurea is contraindicated or not tolerated.
New Listing (Major submission)	METFORMIN XR AND SITAGLIPTIN, metformin XR 1000 mg + sitagliptin 50 mg and metformin XR 1000 mg + sitagliptin 100 mg, tablet, modified release Janumet XR® Merck Sharp and Dohme Australia Pty Ltd	Type 2 diabetes	To request an Authority Required (STREAMLINED) listing for the treatment of type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor, a thiazolidinedione or a glucagon-like peptide-1, despite treatment with metformin and where a combination of metformin and sulfonylurea is contraindicated or not tolerated.
New Listing (Major submission)	MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE, 0.5mL, injection, prefilled syringe Bexsero® Novartis Vaccines and Diagnostics Pty Ltd	Meningococcal B disease	To request the inclusion on the National Immunisation Program (NIP) Schedule for prevention of Meningococcal B disease in infants and adolescents.
Change to Listing (Minor submission)	NARATRIPTAN, 2.5 mg tablet, 2 Naramig® Aspen Pharmacare Australia Pty Ltd	Migraine	Requests to amend the current Authority Required listing of naratriptan to Authority Required (STREAMLINED).

Closing date for consumer comments 9 October 2013

Re-submission (Major submission)	PANITUMUMAB, 100 mg/5 mL and 400 mg/20 mL, injection, vial Vectibix® Amgen Australia Pty Ltd	Metastatic colorectal cancer	Resubmission to request Section 100 (Efficient Funding of Chemotherapy) Authority Required (+/-STREAMLINED) listings for the treatment of KRAS wild-type metastatic colorectal cancer in patients who have failed first-line chemotherapy.
Re-submission (Major submission)	PLERIXAFOR, 24 mg/1.2 mL, injection, vial Mozobil® Sanofi-Aventis Australia Pty Ltd	Multiple myeloma or lymphoma	Resubmission for a Section 100 (Highly Specialised Drugs Program) Authority Required (+/-STREAMLINED) listing for use in combination with G-CSF, in patients with multiple myeloma or lymphoma requiring an autologous stem cell transplant (ASCT) who meet certain criteria.
Re-submission (Minor submission)	QUETIAPINE 50mg, 150mg, 200mg, and 300mg, tablet, modified release Seroquel XR® AstraZeneca	Major depressive disorder	Resubmission for an Authority Required listing for the treatment of recurrent major depressive disorder in patients who have not responded to two other antidepressants. Initiation of treatment is limited to psychiatrists only.
Re-submission (Major submission)	RANIBIZUMAB, 2.3 mg/0.23 mL, injection, vial Lucentis® Novartis Pharmaceuticals Australia Pty Ltd	Diabetic macular oedema	Resubmission to request an Authority Required listing for the treatment, by an ophthalmologist, of visual impairment due to diabetic macular oedema as diagnosed by fluorescein angiography.
Re-submission (Major submission)	RANIBIZUMAB, 2.3 mg/0.23 mL, injection, vial Lucentis® Novartis Pharmaceuticals Australia Pty Ltd	Macular oedema secondary to retinal vein occlusion.	Resubmission to request an Authority Required listing for the treatment, by an ophthalmologist, of visual impairment due to macular oedema secondary to retinal vein occlusion.
Re-submission (Major submission)	SORAFENIB, 200mg, tablet Nexavar® Bayer Australia Limited	Renal cell carcinoma (RCC)	Resubmission to request an Authority Required listing for the treatment, as the sole PBS-subsidised therapy, of Stage IV (advanced) clear cell renal carcinoma in patients who meet certain criteria.

Closing date for consumer comments 9 October 2013

Re-submission (Major submission)	TAPENTADOL HYDROCHLORIDE, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg, tablet, sustained release Palexia® SR BioCSL (Australia) Pty Ltd	Chronic, severe, disabling pain	Resubmission to request a Restricted benefit listing for the treatment of chronic, severe, disabling pain not responding to non-narcotic analgesics.
Change to Listing (Minor submission)	TEMOZOLOMIDE, 180 mg capsule, 5 Temodal® Merck, Sharp & Dohme (Australia) Pty Ltd	Glioblastoma multiforme	Request to extend the Authority Required listing of temozolomide 180 mg on the PBS to include patients with newly diagnosed glioblastoma multiforme concomitant with radiotherapy.
Re-submission (Major submission)	TOBRAMYCIN, 28 mg, powder for inhalation, capsule TOBI®PODHALER® Novartis Pharmaceuticals Australia Pty Ltd	Cystic Fibrosis	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of *Pseudomonas aeruginosa* infection in a patient aged 6 years or older with cystic fibrosis.
Change to Listing (Major submission)	TOCILIZUMAB, 80 mg/4 mL, 200 mg/10 mL and 400 mg/20 mL, injection, vial Actemra® Roche Products Pty Limited	Juvenile idiopathic arthritis (JIA)	To request a Section 100 (Highly Specialised Drugs Program) listing for the treatment of active polyarticular course juvenile idiopathic arthritis (JIA) in: 1) a patient under 18 years or age and; 2) a patient aged 18 years or older who has a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; who meets certain criteria.

Closing date for consumer comments 9 October 2013

New Listing (Minor submission)	TRIGLYCERIDES MEDIUM CHAIN, formula oral liquid 250 mL x 18 tetrapak BetaQuik® Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted benefit listing for: - patients requiring a medium chain triglycerides (MCT) diet such as the ketogenic treatment of intractable childhood epilepsy, cerebrospinal fluid glucose transporter deficiency (GLUT-1) and pyruvate dehydrogenase deficiency (PDHD); - other disorders requiring MCT based diets including chylous ascites, chylothorax, hyperlipoporteinaemia type 1, long chain fatty acid oxidation disorders, fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders
New Listing (Minor submission)	TRIGLYCERIDES LONG CHAIN, formula oral liquid 250 ml x 18 tetrapak CarbZero® Vitaflo Australia Pty Ltd	Medicinal food	To request a Restricted benefit listing for patients requiring a long chain triglycerides (LCT) supplement for dietary management with the ketogenic diet for intractable childhood epilepsy, glucose transporter protein (GLUT-1) deficiency and pyruvate dehydrogenase deficiency (PDHD).