PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2011 PBAC MEETING

Closing date for consumer comments 5 October 2011

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 drug application (Major submission)	ABIRATERONE, tablet, 250 mg (as acetate), Zytiga® Janssen-Cilag Pty Ltd	Anti-cancer drug	Authority Required listing for the initial and continuing treatment, in combination with prednisone or prednisolone, of a patient with metastatic advanced prostate cancer (castration resistant prostate cancer) in whom disease progression has occurred following treatment with docetaxel.
New drug application (Minor submission)	ADRENALINE, I.M. injection , 500 micrograms in 0.3 mL single dose syringe auto-injector, Anapen® 500 Link Medical Products Pty Ltd	Anaphylaxis prevention	List a higher strength (500 microgram) adrenaline auto-injector, under the same listing conditions, with the addition of an extra clause in the restriction to indicate the 500 microgram strength is for use in an adult with a mean weight of at least 60 kg, or in an adult at high risk of severe anaphylaxis in whom the 300 microgram dose may not be sufficient.
New drug application (Minor submission)	AMINO ACID FORMULA with VITAMINS and MINERALS, 240 mL, ProSure® Abbott Australasia Pty Ltd	Medicinal food	Restricted Benefit listing for the treatment of cachexia in patients with advanced pancreatic cancer.
Change to listing (Minor submission) Secretariat listing	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS, compound powder, 400 g, Neocate LCP® AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN, compound powder, 400 g, Neocate LCP+MCT® Nutricia Australia Pty Ltd	Medicinal food	To request the substitution of Neocate LCP and Neocate LCP+MCT with new formulations of the same products (with an altered macronutrient and increased docosahexaenoic acid (DHA) level) under the same PBS listing codes as the currently listed products.
New drug application (Minor submission)	AMINO ACID SYNTHETIC FORMULA, compound powder, 400 g, Neocate Advance Vanilla® Nutricia Australia Pty Ltd	Medicinal food	Include a new vanilla flavoured Neocate product with probiotics, under the same listing conditions as Neocate.
Change to listing (Major submission)	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX, lyophilised powder for I.M injection, 100 units, Botox®	Prevention of headaches in chronic migraine	Extend the current Section 100 listing (Botulinum Toxin Program) to include the prophylaxis of headaches in an adult patient with chronic migraine who meets certain criteria.

	Allergan Australia Pty Ltd		
Re-submission (Minor submission)	BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE, powder for oral inhalation in breath actuated devices, 400 micrograms-12 micrograms per dose (60 doses), Symbicort Turbuhaler 400/12® BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE, oral pressurised inhalation, 200 micrograms-6 micrograms per dose, Symbicort Rapihaler 200/6® AstraZeneca Pty Ltd	Chronic obstructive airways disease	Request a change to the November 2010 PBAC recommendation for the treatment of chronic obstructive pulmonary disease to list a single pack turbuhaler 400/12 which provides 60 doses, sufficient for one month of supply instead of a twin pack. Resubmission to list an alternative delivery device under the same listing conditions as the Turbuhaler including chronic obstructive pulmonary disease.
Re-submission (Minor submission)	CABAZITAXEL, solution concentrate for I.V. infusion, 60 mg in 1.5 mL, Jevtana® Sanofi-Aventis Australia Pty Ltd	Anti-cancer drug	Resubmission for an Authority Required listing for treatment of hormone refractory metastatic carcinoma of the prostate in combination with prednisone/prednisolone in patients previously treated with a docetaxel containing regimen.
New drug application (Minor submission)	DALTEPARIN SODIUM, injection, 10,000 units (anti-Xa) in 1 mL and 12,500 units (anti-Xa) in 0.5 mL, single dose pre-filled syringe, Fragmin® Pfizer Australia Pty Ltd	Blood thinner for use in haemodialysis	Request a Restricted Benefit listing for two higher strengths 10,000 and 12,500 units, of dalteparin for use in haemodialysis.
Change to listing (Minor submission)	DENOSUMAB, injection 60 mg in 1 mL pre-filled syringe, Prolia® Amgen Australia Pty Ltd	Osteoporosis	Request a change from Authority Required to Authority Required (Streamlined) and inclusion in Nurse Practitioner PBS Prescribing.
New drug application (Minor submission) Out of Session	EPOPROSTENOL SODIUM, powder for I.V. infusion, 500 microgram and 1.5 mg (base), with diluent, cassette reservoir and extension set, Flolan Kit® GlaxoSmithKline Australia Pty Ltd	Pulmonary arterial hypertension	Request listing of a new presentation of epoprostenol, that contains diluent and an administration set (one cassette reservoir and one extension set).
Change to listing (Major submission)	EPOPROSTENOL SODIUM, powder for I.V. infusion, 500 micrograms (base) with diluent, 1.5 mg (base) with diluent, Flolan® GlaxoSmithKline Australia Pty Ltd	Pulmonary arterial hypertension secondary to scleroderma spectrum of disease.	Extend the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include the treatment of: 1) WHO functional class III pulmonary arterial hypertension (PAH) secondary to scleroderma spectrum of diseases in patients who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent 2) WHO functional class IV PAH secondary to scleroderma

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			spectrum of diseases.
Re-submission (Major submission)	EVEROLIMUS, tablets, 5 mg and 10 mg, Afinitor®, Novartis Pharmaceuticals Australia Pty Ltd	Anti-cancer	Resubmission for Authority Required listing for the initial and continuing treatment of Stage IV clear cell variant renal cell carcinoma in a patient with a WHO status of 2 or less, who has failed treatment with sunitinib.
Change to listing (Minor submission)	EXENATIDE, injection solution, 5 micrograms and 10 micrograms per dose, pre-filled pen, 60 doses, Byetta 5 microgram® and Byetta 10 microgram® Eli Lilly Australia Pty Ltd	Type 2 diabetes	Request a change from Authority Required to Authority Required (Streamlined) for the current listing for dual combination therapy with metformin or a sulfonylurea, and triple combination therapy with metformin and a sulfonylurea in type II diabetic patients.
New drug application (Minor submission)	FILGRASTIM, injection, 300 micrograms in 0.5 mL and 480 micrograms in 0.8 mL, single use pre-filled syringe, Tevagrastim® Aspen Pharma Pty Ltd	Bone marrow cell stimulator	S100 listing (Highly Specialised Drugs Program) Authority Required listing for a new biosimilar filgrastim, with the same listing conditions as Neupogen and Nivestim.
New drug application (Minor submission)	GEMCITABINE, solution concentrate for I.V. infusion, 200 mg in 5 mL, 1000 mg in 25 mL and 2000 mg in 50 mL (as hydrochloride), Gemcitabine Ebewe® Sandoz Pty Ltd	Anti-cancer drug	Request to list a new concentration of gemcitabine solution concentrated for I.V. infusion under the current listing conditions as the currently listed gemcitabine powder for I.V infusion.
New drug application (Minor submission) Out of Session	GLUCOSE INDICATOR-BLOOD, test strips, 50 and 100 strips, BGStar® Blood Glucose Test Strips Sanofi-Aventis Australia Pty Ltd	Blood glucose indicator	Unrestricted Benefit listing for a new blood glucose indicator, with two pack sizes.
New drug application (Minor submission) Out of Session	GLUCOSE INDICATOR-BLOOD, test strips, 50, Accu-Chek® Aviva Roche Diagnostics Australia Pty Ltd	Blood glucose indicator	List a new glucose indicator-blood test strip as an Unrestricted and Restricted Benefit (GP Management Plan) as the currently listed products.
New drug application (Minor submission)	HYDROXOCOBALAMIN, injection 1 mg (as acetate) in 1 mL, Goldshield Hydrocobalamin® Goldshield Healthcare (Australia) Pty Ltd	Vitamin B12 supplement	Restricted Benefit listing of a new salt (acetate) of hydroxocobalamin injection.
Re-submission (Minor submission)	ICATIBANT, injection, 30 mg in 3 mL (as acetate), single use pre-filled syringe, Firazyr® Shire Australia Pty Ltd	Acute hereditary angioedema	Resubmission for an Authority Required listing for the treatment of hereditary angioedema.
New drug application (Minor submission)	INTERFERON BETA-1a, injection, 30 micrograms (6,000,000 iu) in 0.5 mL single dose pre-filled pen, Avonex®	Multiple sclerosis	Request listing of a new 30 microgram presentation (single dose pre-filled pen) of interferon beta-1a, under the same

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Secretariat listing	Pre-filled pen Biogen Idec Australia Pty Ltd		listing conditions as the 30 micrograms single dose pre-filled syringe.
New drug application (Major submission)	IVABRADINE, tablets, 5 mg and 7.5 mg (as hydrochloride), Coralan ® Servier Laboratories (Australia) Pty Ltd	Heart failure	Authority Required listing for the initial and continuing treatment of symptomatic systolic heart failure in a patient in sinus rhythm, with heart rate at or above 70 bpm stabilised on conventional therapy, which includes a beta blocker (unless intolerant or contraindicated) at a maximum tolerated dose.
Change to listing (Major submission)	LACOSAMIDE, tablets, 50 mg,100 mg, 150 mg and 200 mg, Vimpat ® UCB Australia Pty Ltd	Epilepsy	To request Authority Required (Streamlined) listing and extend the current PBS listing to include for the treatment, in combination with a non-sodium channel target antiepileptic drug, of a patient with partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.
Re-submission (Major submission)	LIRAGLUTIDE (rys), injection, 6 mg in mL, 3 mL, 2 and 3, Victoza® Novo Nordisk Pharmaceuticals Pty Ltd	Type 2 diabetes	Re-submission for an AuthorityRequired listing for treatment of type 2 diabetes: 1) as dual combination therapy with metformin or a sulphonylurea in patients for whom a combination of metformin and a sulphonylurea is contraindicated or not tolerated; 2) as triple combination therapy with metformin and a sulphonylurea.
Re-submission (Major submission)	MANNITOL, capsule containing powder for oral inhalation, 40 mg (for use in inhaler device), Bronchitol® Pharmaxis Ltd	Cystic fibrosis	Resubmission for Authority Required listing for the treatment of cystic fibrosis (CF) as an alternative to dornase alfa in a patient who has previously failed PBS-subsidised initiation criteria for dornase alfa; OR as a monotherapy alternative to dornase alfa in a patient who has discontinued dornase alfa despite a previous successful trial and is considering recommencing therapy; OR as a monotherapy alternative to dornase alfa in a patient currently on dornase alfa or where a change of therapy might improve outcome based on clinical global assessment.
Re-submission (Major submission)	MIGLUSTAT, capsule, 100 mg, Zavesca® Actelion Pharmaceuticals Australia Pty Ltd	Niemann-Pick type C disease	Resubmission to request inclusion on the Life Saving Drugs Program (LSDP) for the treatment of progressive neurological manifestations in adults and paediatric patients with Niemann-Pick type C disease.
Change to listing (Major submission)	MYCOPHENOLATE, tablets (enteric coated), 180 mg and 360 mg (mycophenolic acid), Myfortic®	Lupus nephritis	Extend the current Section 100 and Section 85 Authority Required listings to include the treatment, initiated by a

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	Novartis Pharmaceuticals Australia Pty Ltd		nephrologist, of a patient with biopsy-proven WHO Class III, IV or V lupus nephritis.
New drug application (Minor submission)	NICOTINE, transdermal patch releasing approximately 25 mg per 16 hours, Nicorette® 16 hr Invisipatch® Johnson&Johnson Pacific Pty Ltd	Smoking cessation	Request listing of a new higher 25 mg strength of nicotine patches, under the same listing conditions.
Change to listing (Minor submission)	NILOTINIB, capsule, 200 mg (as hydrochloride monohydrate), Tasigna® Novartis Pharmaceuticals Australia Pty Ltd	Anti-cancer drug	Request to change the current maximum quantity of 112 capsules for 28-days supply to 120 capsules for 30-days supply.
New drug application (Minor submission)	OLANZAPINE, tablet (oral disintergrating), 5 mg, 10 mg, 15 mg and 20 mg, Apo-Olanzapine ODT®, Chemart Olanzapine ODT® and Terry White Chemists Olanzapine ODT® Apotex Pty Ltd	Schizophrenia	Request listing of a new disintegrating tablet formulation of olanzapine under the same listing conditions.
Change to listing (Major submission)	PERTUSSIS VACCINE-ACELLULAR COMBINED with DIPHTHERIA and TETANUS TOXOIDS (Adsorbed), 0.5 mL, Adacel® Sanofi-Aventis Australia Pty Ltd	Vaccine	Request listing on the National Immunisation Program as a single dose booster immunisation against tetanus, diphtheria and pertussis to both parents of newborn infants, where there is no documented evidence of a dTpa booster having been given in the previous 10 years.
Re-submission (Major submission)	PLERIXAFOR, solution for injection, 20 mg in 1 mL, 1.2 mL, Mozobil® Genzyme Australasia Pty Ltd	Mobilises cells used in stem cell transplantation in patients with lymphoma and multiple myeloma	Resubmission for a S100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of lymphoma and multiple myeloma in a patient who requires autologous stem cell transplantation (ASCT) and has failed previous stem cell collection attempts.
New drug application (Major submission)	PRUCALOPRIDE, tablets (film-coated), 1 mg and 2 mg (as succinate), Resotrans® Janssen-Cilag Pty Ltd	Treatment of constipation	Restricted benefit listing for the treatment of moderate to severe chronic constipation in adults who are intolerant to or are not adequately controlled with both bulk forming agents and osmotic laxatives.
Re-submission (Major submission)	QUADRIVALENT HUMAN PAPILLOMAVIRUS (TYPES 6, 11, 16, 18) recombinant vaccine, solution for injection, 0.5 mL, solution for injection pre-filled syringe single dose, Gardasil® CSL Limited	Vaccine	Resubmission for extension of the current listing of Gardasil on the National Immunisation Program (NIP) to include prevention of human papillomavirus (HPV) in males 12 – 13 years of age and a catch – up program over 2 years for Year 9 males.
Change to listing (Major submission)	QUETIAPINE, tablets (modified release), 50 mg, 150 mg, 200 mg, 300 mg and 400 mg (as fumarate), Seroquel XR®	Anti-depressant	Extend the current Authority Required (Streamlined) listing to include the treatment of resistant major depression, as adjunctive therapy.
New drug application	RIFAXIMIN, tablet, 550 mg, Xifaxan®	Hepatic encephalopathy	Restricted benefit listing for the prevention of a further

(Major submission)	Norgine Pty Ltd		recurrence or relapse in a patient who has already had an episode of hepatic encephalopathy.
New drug application (Major submission)	RILPIVIRINE, tablet (film-coated), 25 mg (as hydrochloride), (brand name-to be assigned) Janssen-Cilag Pty Ltd	HIV infection	S100 (Highly Specialised Drugs Program) Authority Required listing for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease.
New drug application (Major submission)	SAPROPTERIN, soluble tablet, 100 mg (as dihydrochloride), Kuvan® Merck Serono Australia Pty Ltd	Treatment of phenylketonuria or tetrahydrobiopterin (BH4) (Rare metabolic disorders)	S100 (Highly Specialised Drugs Program) Authority Required listing for the initial and continuing treatment of: 1) hyperphenylalaninaemia (HPA) due to phenylketonuria in patients who are sapropterin responsive and are: a) 10 years of age or younger b) 11 to 17 years of age c) 18 years of age or older who meet certain criteria. 2) hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU) or tetrahydrobiopterin (BH4) in pregnant women, who meet certain criteria and are sapropterin responsive 3) HPA due to BH4 deficiency in patients who are sapropterin responsive.
New drug application (Minor submission) Out of Session	SAXAGLIPTIN, tablet, 2.5 mg (as hydrochloride), Onglyza® Bristol-Myers Squibb Australia Pty Ltd	Type 2 diabetes	Request listing of a new lower 2.5 mg strength tablet of saxagliptin under the current listing conditions.
New drug application (Minor submission) Secretariat listing	SOMATROPIN (recombinant human growth hormone), solution for injection, 6 mg (18 iu) in 1.03 mL, 12 mg (36 iu) in 1.5 mL and 20 mg (60iu) in 2.5 mL, multi-dose cartridge, Saizen® Merck Serono Australia Pty Ltd	Growth hormone deficiency	Request a Section 100 (Human Growth Hormone) listing of a new presentation and strengths of somatropin (Saizen).
New drug application (Major submission)	TADALAFIL, tablet, 20 mg, Adcirca® Eli Lilly Australia Pty Ltd	Pulmonary arterial hypertension	S100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of WHO functional class III primary pulmonary arterial hypertension (PAH) and WHO functional class III PAH secondary to connective tissue disease in a patient who meets certain criteria.
New drug application (Major submission)	TELAPREVIR, tablet (film-coated), 375 mg, Incivo®	Hepatitis C	S100 (Highly Specialised Drugs Program) Authority Required listing for the treatment, in combination with peginterferon-

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	Janssen-Cilag Pty Ltd		alfa and ribavirin, of chronic hepatitis C in a patient 18 years or older who has compensated liver disease and who has received prior treatment with interferon-alfa or peginterferon-alfa for hepatitis C and meets certain criteria.
New drug application (Major submission)	TENOFOVIR with EMTRICITABINE and RILPIVIRINE, tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine hydrochloride 25 mg, Eviplera® Gilead Sciences Pty Ltd	HIV infection	S100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease.
New drug application (Major submission)	TESTOSTERONE, solution in metered-dose pump, 30 mg in 1.5 mL per dose, 60 doses, 110 mL, Axiron® Eli Lilly Australia Pty Ltd	Testosterone replacement therapy.	Authority Required listing for the treatment of: i) androgen deficiency in males with established pituitary or testicular disorders ii) androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than ageing, and meet certain criteria. iii) micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.
Change to listing (Major submission)	TOCILIZUMAB, concentrate for injection, 80 mg in 4 mL, 200 mg in 10 mL and 400 mg in 20 mL, Actemra® Roche Products Pty Ltd	Juvenile arthritis	Extend the current S100 (Highly Specialised Drugs Program) Authority Required listing to include treatment by a paediatric rheumatologist or under the supervision of a paediatric treatment centre, of severe active systemic juvenile idiopathic arthritis in a patient under18 years of age, who meets certain criteria.
New drug application (Major submission)	VELAGLUCERASE ALFA, powder for IV infusion, 400 units in 4 mL, Vpriv® Shire Australia Pty Limited	Type 1 Gaucher disease	Request inclusion on the Life Saving Drugs Program (LSDP) for the treatment of type 1 Gaucher disease in a patient who meets certain criteria.
New drug application (Major submission)	VINFLUNINE, solution concentration for I.V. infusion, 50 mg in 2 mL and 250 mg in 10 mL (as ditartrate), Javlor® Pierre Fabre Medicament Australia P/L	Anti-cancer drug	Authority Required (Streamlined) listing for the treatment of an adult patient with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen.