

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2016 PBAC MEETING**

Closing date for consumer comments 8 June 2016

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 resubmissions (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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Change to listing (Minor Submission)	ADALIMUMAB 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges 40 mg/0.8 mL injection, 6 x 0.8 mL syringes Humira® AbbVie Pty Ltd	Hidradenitis suppurativa	Resubmission for Authority Required listing for the treatment of moderate to severe hidradenitis suppurativa.
New listing (Minor Submission)	ADRENALINE I.M. injection 150 micrograms in 0.3mL single dose syringe auto-injector I.M. injection 300 micrograms in 0.3mL single dose syringe auto-injector Adrenaline Auto Inject Sun-JV Ranbaxy Australia (Sun Pharma)	Anaphylaxis	Authority Required listing for anaphylaxis.
New listing (Minor Submission)	ALENDRONATE 70 mg tablet: effervescent, 4 Binosto® My Health 365 Pty Ltd	Osteoporosis	Restricted benefit listing for a new formulation of alendronate for the treatment of osteoporosis

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New listing (Minor Submission)	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERAL AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE 34 g bottle, powder for oral liquid, 30 TYR Easy Shake & Go® Orpharma Pty Ltd	Tyrosinaemia	Restricted benefit for patients with tyrosinaemia requiring nutritional support.
New listing (Minor Submission)	APOMORPHINE 50 mg/ 10 mL solution for subcutaneous infusion, 5 x 10 mL syringe MOVAPO™ PFS STADA Pharmaceuticals Australia Pty Limited	Parkinson's disease	Section 100 (Highly Specialised Drugs Program) listing of a new formulation of apomorphine for the treatment of Parkinson's disease
New listing (Major Submission)	BISOPROLOL FUMARATE WITH PERINDOPRIL bisoprolol fumarate 5 mg + perindopril arginine 5mg tablet, 30 bisoprolol fumarate 10 mg + perindopril arginine 5 mg tablet, 30 Cosyrel® Servier Laboratories (Australia) Pty Ltd	Moderate to severe heart failure	Restricted benefit listing for moderate to severe heart failure.

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New listing (Major Submission)	BLINATUMOMAB Injection 38.5 microgram [1 vial] (& inert substance solution [10 mL vial], 1 pack Blincyto® Amgen Australia Pty Ltd	Acute lymphocytic leukaemia	Resubmission for an Authority Required listing for acute lymphoblastic leukaemia.
New listing (Major Submission)	BRIVARACETAM 25 mg tablet, 56 50 mg tablet, 56 75 mg tablet, 56 100 mg tablet, 56 10 mg/mL, 300 mL Briviact® UCB Australia Pty Ltd	Epilepsy	Authority Required (STREAMLINED) listing for treatment of partial epileptic seizures.

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Change to listing (Minor Submission)	BUPRENORPHINE 5 µg/hour patch 10 µg/hour patch 15 µg/hour patch 20 µg/hour patch 25 µg/hour patch 30 µg/hour patch 40 µg/hour patch Norspan® Mundipharma Pty Ltd	Chronic severe disabling pain	Authority Required (STREAMLINED) listing on the palliative care schedule providing up to 3 months' supply
New listing (Major Submission)	DACLIZUMAB 150 mg/mL solution for injection, 1 mL pen-filled pen 150 mg/mL solution for injection, 1 mL syringe Zinbryta® Biogen Australia Pty Ltd	Relapsing-remitting multiple sclerosis	Authority Required listing for the treatment of relapsing-remitting multiple sclerosis.

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New listing (Major Submission)	DACTYLIS GLOMERATA with POA PRATENSIS, LOLIUM PERENNE, ANTHOXANTHUM ODORATUM and PHLEUM PRATENSE 100 IR tablet: sublingual, 3 + 300 IR tablet: sublingual, 28; 300 IR tablet: sublingual, 30 Oralair® Stallergenes Australia Pty Ltd	Allergic rhinitis due to grass pollens	Authority Required (STREAMLINED) listing for allergic rhinitis due to grass pollen.
Change to listing (Minor Submission)	DASATINIB 20 mg tablet, 60 50 mg tablet, 60 70 mg tablet, 60 100 mg tablet, 30 Sprycel® Bristol-Myers Squibb Australia Ltd	Chronic myeloid leukaemia	Resubmission to request an amendment to the current first-line PBS restriction for dasatinib for treatment of patients with chronic myeloid leukaemia to ensure consistency with the first-line listing for the alternative tyrosine kinase inhibitor, imatinib.
Change to listing (Minor Submission)	DENOSUMAB 60 mg/mL injection, 1 x 1 mL syringe Prolia® Amgen Australia Pty Ltd	Osteoporosis	Request to change the current listing for the treatment of osteoporosis to allow prescribing by Nurse Practitioners for initiation of therapy.

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Change to listing (Minor Submission)	DENOSUMAB 120 mg/1.7 mL injection, 1 x 1.7 mL vial Xgeva® Amgen Australia Pty Ltd	Hypercalcaemia of malignancy	Resubmission for an Authority Required (STREAMLINED) listing for the treatment of hypercalcaemia of malignancy which is refractory to intravenous biphosphonate therapy.
Change to listing (Minor Submission)	DIMETHYL FUMARATE 120 mg capsules Tecfidera® Biogen Australia Pty Ltd	Relapsing-remitting multiple sclerosis	Request amendment to the PBS maximum quantity of dimethyl fumarate 120 mg to allow flexibility in dose titration.
Change to listing (Major Submission)	dTpa VACCINE 0.5 mL injection Boostix® GlaxoSmithKline Australia Pty Ltd	Prevention of pertussis	National Immunisation Program listing for maternal vaccination against pertussis (via vaccination of pregnant women, during third trimester of pregnancy).
New listing (Major Submission)	EDOXYBAN 30 mg tablet, 28 60 mg tablet, 28 Lixiana® Daiichi Sankyo Pty Ltd	Prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation	Authority Required (STREAMLINED) listing for prevention of stroke or systemic embolism.

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<p>New listing (Major Submission)</p>	<p>EDOXABAN 30 mg tablet, 28 60 mg tablet, 28 Lixiana® Daiichi Sankyo Pty Ltd</p>	<p>Deep vein thrombosis and pulmonary embolism (venous thromboembolism)</p>	<p>Authority Required (STREAMLINED) listing for treatment of deep vein thrombosis and pulmonary embolism.</p>
<p>New listing (Major Submission)</p>	<p>EMTRICITABINE with RILPIVIRINE and TENOFOVIR emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30 Odefsey® Gilead Sciences Pty Ltd</p>	<p>Human immunodeficiency virus (HIV)</p>	<p>Authority Required (STREAMLINED) listing for treatment of HIV infection.</p>
<p>New listing (Major Submission)</p>	<p>ETANERCEPT 50 mg/mL injection, 1 mL pre-filled syringe, 4 50 mg/mL injection, 1 mL auto-injector, 4 Brenzys® Merck Sharp and Dohme (Australia) Pty Limited</p>	<p>Rheumatoid arthritis; Psoriatic arthritis; Plaque psoriasis; Ankylosing spondylitis; Non-radiographic axial spondyloarthritis; Juvenile idiopathic arthritis; Paediatric plaque psoriasis;</p>	<p>To request listing of Brenzys® (etanercept), a similar biological medicinal product, with the same indications and restrictions as the currently PBS listed brand of etanercept (Enbrel), including the Authority Required listing for rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, juvenile idiopathic arthritis and paediatric plaque psoriasis.</p>

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New listing (Minor Submission)	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS oral liquid: powder for, 30 x 51 g sachets PKU Bettermilk Lite Cortex Health Pty Ltd	Phenylketonuria	Restricted benefit listing for phenylketonuria.
New listing (Major Submission)	GRAZOPREVIR with ELBASVIR grazoprevir 100 mg + elbasvir 50mg tablet, 28 Zepatier® Merck Sharp and Dohme (Australia) Pty Limited	Chronic Hepatitis C virus infection	Authority Required (STREAMLINED) listing for treatment of Chronic Hepatitis C infection.
New listing (Major Submission)	HOUSE DUST MITE AMERICAN with HOUSE DUST MITE EUROPEAN 100 IR tablet: sublingual, 3 + 300 IR tablet: sublingual, 28; 300 IR tablet: sublingual, 30 Actair® Stallergenes Australia Pty Ltd	Allergic rhinitis due to house dust mites	Authority Required (STREAMLINED) listing for allergic rhinitis due to house dust mite.

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Matters Outstanding (Minor Submission)	IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig® Gilead Sciences Pty Ltd	Chronic lymphocytic leukaemia and small lymphocytic lymphoma	Resubmission for Authority Required (STREAMLINED) listing for the treatment chronic lymphocytic leukaemia in patients with progressive disease despite previous treatment.
Matters Outstanding (Minor Submission)	IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig® Gilead Sciences Pty Ltd	Follicular lymphoma	Resubmission for Authority Required (STREAMLINED) listing for the treatment of relapsed/refractory follicular lymphoma that has progressed despite prior treatment with rituximab and an alkylating agent.
Change to listing (Minor Submission)	IPILIMUMAB 50 mg/10 mL injection, 10 mL 200 mg/40 mL injection, 40 mL Yervoy® Bristol-Myers Squibb Australia Ltd	Metastatic melanoma	Request to change the wording in the current restriction from 'the treatment must be as monotherapy' to 'the treatment must be the sole PBS-subsidised therapy for this condition'

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New listing (Major Submission)	IXEKIZUMAB 80 mg/mL injection 2 x 1mL syringe 80 mg/mL injection 2 x 1mL injection device Taltz® Eli Lilly Australia Pty Ltd	Plaque psoriasis	Authority Required listing for severe chronic plaque psoriasis.
Change to listing (Major Submission)	LENALIDOMIDE 5 mg capsule, 21 10 mg capsule, 21 15 mg capsule, 21 25 mg capsule, 21 Revlemid® Celgene Pty Ltd	Relapsed or refractory mantle cell lymphoma	Authority Required listing for treatment of relapsed or refractory mantle cell lymphoma.
New listing (Minor Submission)	LEUPRORELIN AND BICALUTAMIDE Leuprorelin 7.5 mg injection and bicalutamide 50 mg tablet, 28 Leuprorelin 22.5 mg injection and bicalutamide 50 mg tablet, 28 Leuprorelin 22.5 mg injection and bicalutamide 50 mg tablet, 84 Bi ELIGARD CP® Tolmar Australia Pty Ltd	Metastatic (Stage D) prostate cancer	Restricted benefit listing of a combination pack containing leuprorelin and bicalutamide for metastatic (Stage D) prostate cancer.

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New listing (Minor Submission)	MEPOLIZUMAB 100 mg/10 mL vial, powder for injection, 1 Nucala® GlaxoSmithKline Australia Pty Ltd	Severe eosinophilic asthma	Resubmission for a Section 100 (Highly Specialised Drugs Programme) Authority Required listing for the treatment of severe eosinophilic asthma.
New listing (Minor Submission)	MILK POWDER - LACTOSE INTOLERANCE FORMULA Oral liquid: powder for, 900 g S-26 Original LI® Aspen Pharmacare Australia Pty Ltd	Acute and chronic lactose intolerance	Authority Required listing for the treatment of acute and chronic lactose intolerance in infants up to the age of 12 months to replace the current listings for Milk Powder Lactose Free Formula (S-26 LF).
Change to listing (Major Submission)	NIVOLUMAB 40 mg in 4 mL (10mg/mL concentrate for IV infusion) 1 x 4 mL vial 100 mg/10 mL injection (10mg/mL concentrate for IV infusion) 1 x 10 mL vial Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Metastatic renal cell carcinoma	Authority Required (STREAMLINED) for treatment of advanced or metastatic clear cell variant renal cell carcinoma.

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Matters Outstanding (Minor Submission)	OLAPARIB 50mg capsule, 4 x 112 capsules Lynparza™ AstraZeneca Pty Ltd	Ovarian, fallopian tube or primary peritoneal cancer	Resubmission for an Authority Required (STREAMLINED) listing for the treatment of platinum-sensitive relapsed ovarian, fallopian tube or primary peritoneal cancer with high-grade serous features or a high grade serous component.
Change to listing (Major Submission)	OMALIZUMAB 75 mg/0.5mL injection, 1 x 0.5 mL syringe 150 mg/mL injection, 1 x 1 mL syringe Xolair® Novartis Pharmaceuticals Australia Pty Ltd	Paediatric severe allergic asthma	Authority Required listing for treatment of severe allergic asthma in patients aged 6 to less than 12 years.
Change to listing (Major Submission)	PERAMPANEL 2 mg tablet, 7 4 mg tablet, 28 6 mg tablet, 28 8 mg tablet, 28 10 mg tablet, 28 12 mg tablet, 28 Fycompa® Eisai Australia Pty Limited	Epilepsy	Authority Required (STREAMLINED) for treatment of epilepsy with Primary Generalised Tonic-Clonic seizures.

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New listing (Minor Submission)	PROGESTERONE 200 mg capsule, 42 Utrogestan® Besins Healthcare	Assisted reproduction	Resubmission for Section 100 (IVF/GIFT) Authority Required (STREAMLINED) listing for luteal phase support as part of an assisted reproductive technology treatment cycle.
New listing (Minor Submission)	RIBAVIRIN 200 mg tablet Ibavyr® Clinect Pty Ltd	Chronic hepatitis C virus infection	Authority Required section 85 and section 100 (Highly Specialised Drugs) listing of a new strength of ribavirin for the same indications as the currently listed strengths.
Change to listing (Minor Submission)	RIBAVIRIN 400 mg tablet 600 mg tablet Ibavyr® Clinect Pty Ltd	Chronic hepatitis C virus infection	Authority Required section 85 and section 100 (Highly Specialised Drugs) listing of ribavirin, in combination with daclatasvir and sofosbuvir, for the treatment of genotypes 2, 3, 4, 5 and 6 hepatitis C viral infection in patients 18 years or older who have decompensated liver disease.

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Matter arising (Non major/minor Submission)	RITUXIMAB 500 mg/50 mL injection: 1 x 50 mL vial Mabthera® Roche Products Pty Ltd.	Various	To consider the available evidence of the efficacy of rituximab for indications for which it is not currently listed (as per paragraph 7.10, rituximab public summary document, March 2015).
New listing (Minor Submission)	RUXOLITINIB 10 mg tablet, 56 Jakavi® Novartis Pharmaceuticals Australia Pty Ltd	Myelofibrosis	Authority Required listing for a new strength of ruxolitinib for the same indications as the currently listed strengths of ruxolitinib.
New listing (Minor Submission)	SACUBITRIL with VALSARTAN sacubitril 24 mg + valsartan 26 mg tablet, 56 sacubitril 49 mg + valsartan 51 mg, tablet, 56 sacubitril 97 mg + valsartan 103 mg, tablet, 56 Entresto® Novartis Pharmaceuticals Australia Pty Ltd	Chronic heart failure	Resubmission for Authority Required (STREAMLINED) listing for the treatment of chronic heart failure with reduced ejection fraction.

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New listing (Major Submission)	TALIMOGENE LAHERPAREPVEC 1 million PFU/mL solution for injection, 1 x 1 mL vial Imlygic® Amgen Australia Pty Ltd	Melanoma	Authority Required listing for treatment of Unresectable Stage III or Stage IV melanoma without visceral metastases.
New listing (Major Submission)	TENOFOVIR with EMTRICITABINE tenofovir alafenamide 10 mg + emtricitabine 200 mg tablet, 30 tenofovir alafenamide 25 mg + emtricitabine 200 mg tablet, 30 Descovy® Gilead Sciences Pty Ltd	Human immunodeficiency virus (HIV)	Authority Required (STREAMLINED) listing for treatment of HIV infection.
Change to listing (Major Submission)	TENOFOVIR with EMTRICITABINE tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 Truvada® Gilead Sciences Pty Ltd	HIV pre-exposure prophylaxis	Authority Required listing to reduce the risk of sexually acquired HIV infection in adults at substantial risk of HIV infection.

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Matter arising (Major Submission)	TRAMETINIB 2 mg tablet, 90 0.5 mg tablet, 90 Mekinist® Novartis Pharmaceuticals Australia Pty Ltd	Melanoma	To seek PBAC reconsideration of the cost-effectiveness of trametinib for the treatment of metastatic melanoma and to fulfil the requirements of the Managed Entry Scheme.
New listing (Major Submission)	ULIPRISTAL 5 mg tablet, 28 Esmya® Vifor Pharma Pty Ltd	Moderate to severe symptoms of uterine fibroids	Authority Required (STREAMLINED) listing for treatment of moderate to severe symptoms of uterine fibroids.
New listing (Minor Submission)	WHEY PROTEIN FORMULA SUPPLEMENTED WITH MEDIUM CHAIN TRIGLYCERIDES, CARBOHYDRATE, VITAMINS AND MINERALS 24 x 200 mL bottles, oral liquid Infatrini Peptisorb® Nutricia Australia Pty Ltd	Dietary management of conditions requiring a source of medium chain triglycerides	Restricted benefit for the dietary management of infants with gastrointestinal malabsorption or maldigestion requiring a source of medium chain triglycerides
Sub-committee report (DUSC analysis)	Apixaban (Eliquis®) Dabigatran (Pradaxa®) Rivaroxaban (Xarelto®)	Stroke prevention	To review the predicted versus actual use of novel oral anticoagulants in stroke prevention or systolic embolism in patients with non-valvular atrial fibrillation.

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<p>Sub-committee report (DUSC analysis)</p>	<p>Abiraterone (Zytiga®) Cabazitaxel (Jevtana®) Enzalutamide (Xtandi®)</p>	<p>Metastatic prostate cancer</p>	<p>To compare the predicted versus actual use of medicines for metastatic prostate cancer.</p>
<p>Sub-committee report (DUSC analysis)</p>	<p>Bimatoprost Latanoprost Tafluprost Travoprost Betaxolol Timolol Apraclonidine Brimonidine Brinzolamide Dorzolamide Pilocarpine Bimatoprost+Timolol Brimonidine+Timolol Brimonidine+Brinzolamide Dorzolamide+Timolol Travoprost+Timolol Latanoprost+Timolol Brinzolamide+Timolol (all current and previously listed brands including generic versions)</p>	<p>Glaucoma</p>	<p>To review the utilisation of medicines used to treat glaucoma and elevated intraocular pressure.</p>