PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 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.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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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	Ulcerative colitis	Resubmission to request an Authority Required listing for the treatment of patients with moderate to severe ulcerative colitis.
Change to listing (Major 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	Authority Required listing for the treatment of moderate to severe hidradenitis suppurativa.

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MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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Change to listing (Minor Submission)	ADRENALINE 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe EpiPen® EpiPen® Jr Alphapharm Pty Limited	Anaphylaxis	To request inclusion in the Prescriber Bag (Emergency Drug Supply) for the treatment of anaphylaxis.
Matters Outstanding (Minor Submission)	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid: powder for, 30 x 20 g sachets PKU Go® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for phenylketonuria.
Matters Outstanding (Minor Submission)	AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE oral liquid, 20 x 500 mL PKU Baby® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for phenylketonuria.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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Change to listing (Minor Submission)	APREPITANT 165 mg capsule, 1 Emend® Merck Sharp and Dohme (Australia) Pty Limited	Chemotherapy induced nausea and vomiting	Resubmission to request an extension to the current Section 100 (Chemotherapy - Related Benefits) and General Schedule PBS listings to include use with carboplatin/oxaliplatin regimens from the first chemotherapy cycle without having a prior episode of chemotherapy induced nausea and vomiting.
New Listing (Minor Submission)	ARMODAFINIL 50 mg tablet, 30 150 mg tablet, 30 250 mg tablet, 30 Nuvigil® TEVA Pharma Australia Pty Ltd	Narcolepsy	Resubmission to request an Authority Required listing for the treatment of narcolepsy.
Other business (Minor Submission) WITHDRAWN	BENDAMUSTINE powder for injection 25 mg vial, 1 powder for injection 100 mg vial, 1 Ribomustin® Janssen-Cilag Australia Pty Ltd	Non-Hodgkin's lymphoma and mantle cell lymphoma	To request the PBAC reconsider the basis of the Risk Sharing Arrangement recommended at the July 2015 meeting.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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Change to listing (Minor Submission)	BEVACIZUMAB 100 mg/4 mL injection, 1 x 4 mL vial 400 mg/16 mL injection, 1 x 16 mL vial Avastin® Roche Products Pty Limited	Advanced cervical cancer	Resubmission to request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with persistent, recurrent or metastatic cervical cancer not amenable to curative treatment with surgery and/or radiation, in combination with platinum-based chemotherapy or topotecan plus paclitaxel.
New listing (Minor Submission)	BORTEZOMIB 3 mg injection, 3 mg vial Velcade® Janssen-Cilag Australia Pty Ltd	Multiple myeloma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for a new strength (3 mg vial) of bortezomib for multiple myeloma.
Change to listing (Minor Submission)	CERTOLIZUMAB PEGOL 200 mg/mL injection, 2 x 1 mL syringes Cimzia® UCB Australia Pty Ltd	Moderate to severe active rheumatoid arthritis, ankylosing spondylitis and severe psoriatic arthritis	To request an additional PBS item number for the loading dose of Cimzia for the three currently listed indications.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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Change to listing (Major Submission)	CETUXIMAB 100 mg/20 mL injection, 1 x 20 mL vial 500 mg/100 mL injection, 1 x 100 mL vial Erbitux® Merck Serono Australia Pty Ltd	Recurrent and/or metastatic squamous cell carcinoma of the head and neck	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for use in combination with platinum-based chemotherapy for the treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck.
New listing (Major Submission)	COBIMETINIB and VEMURAFENIB cobimetinib 20 mg tablet, 63 vemurafenib 240 mg tablet, 56 Cotellic® Zelboraf® Roche Products Pty Limited	Melanoma	Authority Required (STREAMLINED) listing for the treatment BRAF V600 mutation positive unresectable Stage III or IV malignant melanoma.
New listing (Minor Submission)	DARUNAVIR + COBICISTAT darunavir 800 mg + cobicistat 150 mg tablet, 30 Prezcobix® Janssen-Cilag Australia Pty Ltd	HIV infection	Resubmission to request Section 100 (Highly Specialised Drugs Programme) Authority Required (STREAMLINED) listing for the treatment of HIV infection in combination with other antiretroviral agents in patients who are antiretroviral treatment naïve or in patients who are treatment experienced with no darunavir resistance associated mutations.

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MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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Change to listing (Major Submission)	DENOSUMAB 120 mg/1.7 mL injection, 1 x 1.7 mL vial Xgeva® Amgen Australia Pty Ltd	Hypercalcaemia of malignancy	Authority Required (STREAMLINED) listing for the treatment of hypercalcaemia of malignancy which is refractory to intravenous biphosphonate therapy.
New listing (Major Submission)	DEXAMETHASONE 700 microgram implant, 1 Ozurdex® Allergan Australia Pty Ltd	Diabetic macular oedema	Resubmission for Authority Required listing for the treatment of visual impairment due to diabetic macular oedema in patients with pseudophakia (i.e. artificial lens following cataract surgery) or who are scheduled for cataract surgery.
Change to recommended listing (Other Submission)	ECULIZUMAB 300 mg/30 mL injection, 1 x 30 mL vial Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	atypical Haemolytic Uraemic Syndrome (aHUS) following kidney transplantation	To provide the PBAC with updated data regarding the use of eculizumab in the context on renal transplant.
New listing (Major Submission)	ELOSULFASE ALFA 5 mg/5 mL injection, 5 mL vial Vimizim® Biomarin Pharmaceuticals Australia Pty Ltd	Mucopolysaccaridosis type IVA; Morquio A syndrome	Resubmission for Section 100 (Highly Specialised Drugs Programme) Authority Required listing for the treatment of patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A Syndrome).

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MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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Change to listing (Major Submission)	ETANERCEPT 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack; 50 mg in 1 mL single use pre-filled syringes, 4; 50 mg in 1 mL single use auto-injector, 4 Enbrel® Pfizer Australia Pty Ltd	Active non-radiographic axial spondyloarthritis	Resubmission for Authority Required (STREAMLINED) listing for the treatment of adults with active non-radiographic axial spondyloarthritis.
New listing (Major Submission)	EVOLOCUMAB 140 mg/1 mL injection, 1 mL injection device, 1 Repatha® Amgen Australia Pty Ltd	Familial hypercholesterolaemia	Resubmission for Authority Required listing for the treatment of familial hypercholesterolaemia.
New listing (Minor Submission)	EXENATIDE 2 mg powder for injection pre-filled pen Bydureon® AstraZeneca Australia Pty Ltd	Type 2 diabetes mellitus	To request an Authority Required (STREAMLINED) listing of a new dual chamber pen presentation.

Closing date for consumer comments 10 February 2016

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Other business (Minor Submission)	FOLLITROPIN ALFA 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge GONAL-f® Merck Serono Australia Pty Ltd	Assisted reproduction	To request that follitropin alfa not be 'a-flagged' to Bemfola® or any future follitropin alfa biosimilar.
New listing (Minor Submission)	FOLLITROPIN ALFA 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices Bemfola® Finox Biotech Australia Pty Ltd	Assisted reproduction	To request listing of Bemfola® (follitropin alfa), a similar biological medicinal product, with the same indications and restrictions as the currently PBS listed brand of follitropin alfa (Gonal-f), including a Section 100 (IVF Program) Authority Required (STREAMLINED) listing for controlled ovarian hyperstimulation in women undergoing assisted reproductive technologies and General Schedule Restricted Benefit listings for anovulatory infertility and hypogonadotrophic hypogonadism.

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Closing date for consumer comments 10 February 2016

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New listing (Minor Submission)	GLUCOSE INDICATOR BLOOD 100 strips VivaChek Ino Boian Surgical Pty Ltd	Diabetes	To request PBS listing of a new brand of blood glucose test strips.
Change to Listing (Major Submission)	GONADOTROPHIN gonadotrophin-menopausal human 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack Menopur® Ferring Pharmaceuticals Pty Ltd	Anovulatory infertility	Restricted benefit listing for anovulatory infertility.
New listing (Major Submission) WITHDRAWN	GRAZOPREVIR + ELBASVIR grazoprevir 100 mg + elbasvir 50 mg 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 virus infection.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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Closing date for consumer comments 10 February 2016

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New listing (Minor Submission)	IBRUTINIB 140 mg capsules, 90 Imbruvica® Janssen-Cilag Australia Pty Ltd	Chronic lymphocytic leukaemia and small lymphocytic lymphoma	Resubmission to request Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory chronic lymphocytic leukaemia and relapsed or refractory small lymphocytic lymphoma.
New listing (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.
New listing (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.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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New listing (Minor Submission)	LENVATINIB 4 mg capsule, 30 10 mg capsule, 30 Lenvima® Eisai Australia Pty Ltd	Differentiated thyroid cancer	Resubmission for Authority Required listing for the treatment of radioactive iodine refractory differentiated thyroid cancer.
Change to listing (Minor Submission)	LEUPRORELIN 22.5 mg injection: modified release [1 x 22.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack 7.5 mg injection: modified release [1 x 7.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack Lucrin® AbbVie Pty Ltd	Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate; Central precocious puberty	To request a restricted Benefit listing to replace current Authority Required and Authority Required (STREAMLINED) listings, in line with the current listing for goserelin.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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Change to listing (Major Submission)	LINAGLIPTIN LINAGLIPTIN and METFORMIN linagliptin 5 mg tablet, 30 linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 Trajenta® Trajentamet® Boehringer Ingelhiem Pty Ltd	Type 2 diabetes mellitus	Authority Required (STREAMLINED) listing for use in combination with insulin in patients with type 2 diabetes mellitus.
Change to listing (Major Submission)	LINAGLIPTIN LINAGLIPTIN and METFORMIN linagliptin 5 mg tablet, 30 linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 Trajenta® Trajentamet® Boehringer Ingelhiem Pty Ltd	Type 2 diabetes mellitus	Resubmission for Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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New listing (Major Submission)	LIPEGFILGRASTIM 6 mg/0.6 mL, 1 x 0.6 mL injection Lonquex® TEVA Pharma Australia Pty Ltd	Neutropenia	Section 100 (Highly Specialised Drugs Programme) Authority Required listing for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in line with the current listings for pegfilgrastim.
New listing (Major Submission)	LUMACAFTOR + IVACAFTOR lumacaftor 200 mg + ivacaftor 125 mg tablet, 4 x 28 Orkambi® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic Fibrosis	Authority Required listing for the treatment of cystic fibrosis in patients aged 12 years and older who are homozygous for the F508del mutation in the CFTR gene.
Change to listing (Minor Submission)	LUTROPIN ALFA and FOLLITROPIN ALFA + LUTROPIN ALFA lutropin alfa 75 international units injection [1 x 75 international units vial] (&) inert substance diluent [1 x 1 mL vial], 1 follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance diluent [1 vial], 1 Luveris® Pergoveris® Merck Serono Australia Pty Ltd	Assisted reproduction	To request increased maximum quantities for Luveris® and Pergoveris®.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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New listing (Major Submission)	MEPOLIZUMAB 100 mg/10 mL vial, powder for injection, 1 Nucala® GlaxoSmithKline Australia Pty Ltd	Severe eosinophilic asthma	Section 100 (Highly Specialised Drugs Programme) Authority Required listing for the treatment of severe eosinophilic asthma.
New listing (Minor Submission)	METHOTREXATE solution for injection, 7.5 mg/0.15 mL solution for injection, 10 mg/0.2 mL solution for injection, 15 mg/0.3 mL solution for injection, 20 mg/0.4 mL solution for injection, 25 mg/0.5 mL Trexject® Link Medical Products Pty Ltd	Rheumatoid arthritis or psoriasis	Restricted Benefit listing for the treatment of rheumatoid arthritis or psoriasis for use in patients where the oral tablet form of methotrexate is unsuitable.
New listing (Minor Submission)	MORPHINE HYDROCHLORIDE 10 mg/1 mL solution for injection, 5 x 1 mL ampoules 20 mg/1 mL solution for injection, 5 x 1 mL ampoules 50 mg/5 mL solution for injection, 5 x 5 mL ampoules 100 mg/5 mL solution for injection, 5 x 5 mL ampoules Morphine Juno® Juno Pharmaceuticals Pty Ltd	Pain	To request an unrestricted benefit listing of a new brand and additional strengths of morphine injection.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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New listing (Major Submission)	NINTEDANIB 100 mg capsule, 60 150 mg capsule, 60 Ofev® Boehringer Ingelhiem Pty Ltd	Non-small cell lung cancer	Resubmission for Authority Required listing for patients with locally advanced or metastatic non-small cell lung cancer.
New listing (Major Submission)	NIVOLUMAB 40 mg in 4 mL (10 mg/mL concentrate for IV infusion) 100 mg in 10 mL (10 mg/mL concentrate for IV infusion) Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Squamous non-small cell lung cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic squamous non-small cell lung cancer with progression on or after prior chemotherapy.
New listing (Major Submission)	NIVOLUMAB 40 mg in 4 mL (10 mg/mL concentrate for IV infusion) 100 mg in 10 mL (10 mg/mL concentrate for IV infusion) Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Non-squamous non-small cell lung cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic non-squamous non-small cell lung cancer with progression on or after prior chemotherapy.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

Closing date for consumer comments 10 February 2016

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New listing (Major Submission)	OCRIPLASMIN 0.5 mg/0.2 mL injection, 1 x 0.2 mL vial Jetrea® Alcon Laboratories (Australia) Pty Ltd	Vitreomacular traction	Resubmission for Authority required listing for the treatment of vitreomacular traction.
New listing (Major Submission)	OLAPARIB 50 mg capsule, 4 x 112 Lynparza® AstraZeneca Pty Ltd	Ovarian, fallopian tube or primary peritoneal cancer	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)	PEMBROLIZUMAB 50 mg injection: powder for, 1 vial Keytruda® Merck Sharp and Dohme (Australia) Pty Limited	Melanoma	To seek PBAC reconsideration of the cost-effectiveness of pembrolizumab for the treatment of unresectable stage III or stage IV metastatic melanoma and to fulfil the requirements of the Managed Entry Scheme.
New listing (Minor Submission)	PEMETREXED 1000 mg powder for I.V. infusion Pemetrexed MYX™ Mayne Pharma International Pty Ltd	Non-small-cell lung cancer and mesothelioma	To request listing of an additional strength of pemetrexed, 1000 mg, on the PBS. This accompanies a request for generic listing of Pemetrexed MYX at 100 mg and 500 mg.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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Closing date for consumer comments 10 February 2016

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New listing (Minor Submission)	PEMETREXED 1000 mg powder for injection DBL™ Pemetrexed Hospira Pty Limited	Non-small-cell lung cancer and mesothelioma	To request listing of an additional strength of pemetrexed, 1000 mg, on the PBS.
New listing (Minor Submission)	PIRFENIDONE 267 mg capsules, 270 Esbriet® Roche Products Pty Limited	Idiopathic pulmonary fibrosis	Resubmission to request an Authority Required listing for the treatment of idiopathic pulmonary fibrosis.
Change to listing (Minor Submission)	POMALIDOMIDE 3 mg capsule, 21 4 mg capsule, 21 Pomalyst® Celgene Pty Ltd	Multiple myeloma	To request a change to the current PBS restriction for pomalidomide in order to allow access for patients experiencing disease progression more than 6 months after cessation of lenalidomide and/or bortezomib.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

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Submission type (new listing, change to listing)	**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 (Minor Submission)	PRALATREXATE 20 mg/mL injection, 1 mL vial Folotyn® Mundipharma Pty Ltd	Peripheral T-cell lymphoma	Resubmission to request Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with peripheral T-cell lymphoma.
New listing (Major Submission)	PROGESTERONE 200 mg capsule, 42 Utrogestan® Besins Healthcare Australia Pty Ltd	Assisted reproduction	Section 100 (IVF) Authority Required (STREAMLINED) listing for luteal phase support as part of an assisted reproductive technology treatment cycle.
Change to recommended listing (Major Submission)	RIOCIGUAT 0.5 mg tablet, 42 and 84 packs 1 mg tablet, 42 and 84 packs 1.5 mg tablet, 42 and 84 packs 2 mg tablet, 42 and 84 packs 2.5 mg tablet, 42 and 84 packs Adempas® Bayer Australia Ltd	Chronic thromboembolic pulmonary hypertension (CTEPH)	Resubmission for Section 100 (Highly Specialised Drugs Programme) Authority Required (STREAMLINED) listing for the treatment of inoperable CTEPH or persistent CTEPH subsequent to pulmonary endocardectomy.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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New listing (Major Submission)	SACUBITRIL + 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	Authority Required (STREAMLINED) listing for the treatment of chronic heart failure with reduced ejection fraction.
Change to listing (Major Submission)	SECUKINUMAB 150 mg/mL injection, 1 x 1 mL injection device 150 mg/mL injection, 2 x 1 mL injection devices Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd	Ankylosing spondylitis	Authority Required listing for the treatment of adults with active ankylosing spondylitis.
Change to listing (Major Submission)	SECUKINUMAB 150 mg/mL injection, 1 x 1 mL injection device 150 mg/mL injection, 2 x 1 mL injection devices Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd	Psoriatic arthritis	Authority required listing for the treatment of adults with severe active psoriatic arthritis.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

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Change to listing (Minor Submission)	SECUKINUMAB 150 mg/mL injection, 2 x 1 mL injection devices Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd	Severe chronic plaque psoriasis	To request an increase in the maximum quantity from 1 pack to 5 packs for initial treatment.
New listing (Major Submission)	SELEXIPAG 200 microgram tablet, 140 200 microgram tablet, 60 400 microgram tablet, 60 600 microgram tablet, 60 800 microgram tablet, 60 1000 microgram tablet, 60 1200 microgram tablet, 60 1400 microgram tablet, 60 1600 microgram tablet, 60 Uptravi® Actelion Pharmaceutical Australia Pty Ltd	Pulmonary arterial hypertension	Section 100 (Highly Specialised Drugs Programme) Authority Required listing for use as an add-on therapy to endothelin receptor antagonists (ambrisentan, bosentan or macitentan) or to phosphodiesterase type 5 inhibitors (sildenafil and tadalafil) for the treatment of pulmonary arterial hypertension.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

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New listing (Minor Submission)	SOMATROPIN 0.4 mg/0.25 mL powder for injection & diluent in prefilled syringe Genotropin MiniQuick® Pfizer Australia Pty Ltd	Growth hormone deficiency, Turner syndrome, Prader-Willi syndrome and chronic renal insufficiency	To request a Section 100 (Growth Hormone Programme) Authority Required listing for the 0.4 mg strength Genotropin MiniQuick.
Other business (Minor Submission)	SOMATROPIN All PBS listed Growth Hormone products Various sponsors Australasian Paediatric Endocrine Group	Biochemical Growth Hormone Deficiency, Infants with Chronic Renal Insufficiency awaiting renal transplantation	To request a change in the restriction text for Growth Hormone (GH) eligibility in children with: Biochemical Growth Hormone Deficiency and Infants with Chronic Renal Insufficiency (CRI) awaiting renal transplantation.
New listing (Minor Submission)	TACROLIMUS 750 microgram capsule 2 mg capsule Tacrolimus Sandoz® Sandoz Pty Ltd	Liver, kidney, lung or heart allograft transplantation in adults and children	To request the listing of additional strengths of tacrolimus 0.75 mg and 2 mg on the PBS under General schedule and Section 100 (Highly Specialised Drugs Programme).

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Change to listing (Major Submission)	TAMOXIFEN 20 mg tablet, 30 Nolvadex-D® AstraZeneca Pty Ltd	Prevention of breast cancer	Restricted benefit listing for the primary prevention of breast cancer in patients with moderate or high risk of developing breast cancer.
New listing (Minor Submission)	THYROXINE SODIUM 25 microgram tablet, 200 Eltroxin® Aspen Pharmacare Australia Pty Ltd	Thyroid hormone deficiency thyroid stimulating hormone-responsive tumours of the thyroid	Resubmission to request an unrestricted benefit listing for thyroxine sodium 25 micrograms.
Change to listing (Major Submission)	TIOTROPIUM BROMIDE tiotropium 2.5 microgram/actuation inhalation: solution, 60 actuations Spiriva® Respimat® Boehringer Ingelhiem Pty Ltd	Asthma	Resubmission to request a Restricted benefit listing for the treatment of severe asthma.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

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New listing (Minor Submission)	TOCILIZUMAB 162 mg/0.9 mL injection, 4 x 0.9 mL syringes Actemra® Roche Products Pty Limited	Rheumatoid arthritis	To request an Authority Required listing for a subcutaneous injection presentation of tocilizumab.
Matters Outstanding (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN oral liquid, 12 x 500 mL pouches Peptamen® Junior Liquid Peptamen® Junior Advance Nestlé Health Science (Nestlé Australia Ltd)	Medicinal food	To request a Restricted Benefit listing for dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.
New Listing (Major Submission)	TRIPTORELIN ACETATE 100 microgram/1 mL injection, 28 x 1 mL syringes Decapeptyl® Ferring Pharmaceuticals Pty Ltd	Assisted reproduction	Section 100 (IVF) Authority Required (STREAMLINED) listing for Assisted Reproductive Technology.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2016 PBAC MEETING

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Change to listing (Major Submission)	VILDAGLIPTIN VILDAGLIPTIN with METFORMIN vildagliptin 50 mg tablet, 60 vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 Galvus® Galvumet® Novartis Pharmaceuticals Australia Pty Ltd	Type 2 diabetes mellitus	Resubmission for Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus.
New listing (Major Submission)	VISMODEGIB 150 mg capsule, 28 Erivedge® Roche Products Pty Limited	Metastatic or locally advanced basal cell carcinoma	Authority Required listing for the treatment of metastatic or locally advanced basal cell carcinoma.
Sub-committee report (DUSC analysis)	Adalimumab (Humira®) Certolizumab pegol (Cimzia®) Etanercept (Enbrel®) Golimumab (Simponi®) Infliximab (Remicade®, Inflectra®)	Ankylosing spondylitis	To examine the PBS use of biological disease modifying anti-rheumatic drugs (bDMARDs) used to treat ankylosing spondylitis.

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MARCH 2016 PBAC MEETING

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Sub-committee report (Addendum to the October 2015 DUSC analysis)	Adalimumab (Humira®) Certolizumab pegol (Cimzia®) Etanercept (Enbrel®) Golimumab (Simponi®) Infliximab (Remicade®, Inflectra®)	Psoriatic arthritis	To assess the utilisation of disease modifying anti-rheumatic drugs (DMARD) prior to initiation of biological DMARDs for psoriatic arthritis.
Sub-committee report (DUSC analysis)	Donepezil, rivastigmine, galantamine and memantine (all current and previously listed brands)	Dementia	To review the utilisation of medicines for the treatment of Alzheimer disease 24 months after changes to their Pharmaceutical Benefits Scheme (PBS) restrictions arising from the Post Market Review of Anti-dementia drugs. The changes were implemented on 1 May 2013.
Sub-committee report (DUSC analysis)	Varenicline (Champix®) Bupropion (Zyban®) Nicotine replacement therapy (Nicotinell®, Nicabate® QuitX® Nicorette®)	Smoking cessation	To report the utilisation of R/PBS subsidised smoking cessation therapies and to consider the impact of nicotine replacement therapy products changing from Authority Required to Authority Required (STREAMLINED) on 1 December 2013.
Sub-committee report (DUSC analysis)	Ticagrelor (Brilinta®)	Acute coronary syndrome	To review the predicted versus actual use of ticagrelor for acute coronary syndrome.