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

Closing date for consumer comments 5 October 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)	AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS without PHENYLALANINE Bottles containing oral powder 34 g, 30 PKU EASY® SHAKE & GO AMINO ACID FORMULA with FAT, CARBOHYDRATE without PHENYLALANINE Tablet: modified release, 70.8 g protein per 100 g, 110 g PKU EASY® MICROTABS PROTEIN FORMULA with AMINO ACIDS, CARBOHYDRATES, VITAMINS and MINERALS without PHENYLALANINE, and SUPPLEMENTED with DOCOSAHEXAENOIC ACID Oral liquid 130 mL, 30 PKU EASY® Orpharma Pty Ltd	Phenylketonuria	To request an increase in maximum quantities for PKU EASY SHAKE & GO, PKU EASY MICROTABS, and PKU EASY.

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Change to listing (Major Submission)	ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe Humira® AbbVie Pty Ltd	Hidradenitis suppurativa	Resubmission to request an Authority Required listing for the treatment of moderate to severe hidradenitis suppurativa.
New listing (Minor Submission)	APOMORPHINE Injection containing apomorphine (as hydrochloride) 100 mg in 20 mL Apomine® Pfizer Australia Pty Ltd	Parkinson disease	To request a General Schedule and Section 100 (Highly Specialised Drugs Program) listing of an additional strength of apomorphine.
New listing (Major Submission)	APREMILAST Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg Otezla® Celgene Pty Ltd	Plaque psoriasis	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of moderate to severe plaque psoriasis.

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Change to recommended listing (Minor Submission)	BLINATUMOMAB Injection 38.5 microgram [1 vial] and inert substance solution [10 mL vial] Blincyto® Amgen Australia Pty Ltd	Relapsed or refractory Philadelphia-chromosome negative B-precursor acute lymphoblastic leukaemia	Resubmission to request a revision to the July 2016 PBAC recommendation.
Change to listing (Major Submission)	BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris® Takeda Pharmaceuticals Australia Pty Ltd	Hodgkin lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of relapsed or refractory Hodgkin lymphoma for autologous stem cell transplant-naïve patients.
Change to listing (Major Submission)	BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris® Takeda Pharmaceuticals Australia Pty Ltd	Hodgkin lymphoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of relapsed or refractory Hodgkin lymphoma following autologous stem cell transplant failure.
New listing (Major Submission)	CALCIPOTRIOL with BETAMETHASONE Foam containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g Enstilar® LEO Pharma Pty Ltd	Psoriasis	To request a Restricted Benefit listing for patients with chronic stable plaque type psoriasis vulgaris that is inadequately controlled with either a Vitamin D analogue or potent topical corticosteroid monotherapy.

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New listing (Major Submission)	CARFILZOMIB Powder for I.V. infusion 30 mg Powder for I.V. infusion 60 mg Kyprolis® Amgen Australia Pty Ltd	Multiple myeloma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of multiple myeloma in patients failing one prior line of treatment.
New listing (Major Submission)	CERITINIB Capsule 150 mg Zykadia® Novartis Pharmaceuticals Australia Pty Ltd	Non-small cell lung cancer (NSCLC)	To request an Authority Required listing for anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic NSCLC patients with disease progression, following treatment with a prior ALK inhibitor.
New listing (Minor Submission)	CETUXIMAB Injection 100 mg in 20 mL Injection 500 mg in 100 mL Erbitux® Merck Serono Australia Pty Ltd	Recurrent or metastatic squamous cell carcinoma of the head and neck	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck.
New listing (Major Submission)	EDOXABAN Tablet 30 mg Tablet 60 mg Lixiana® Daiichi Sankyo Pty Ltd	Prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation (NVAF)	To request an Authority Required (STREAMLINED) listing for prevention of stroke or systemic embolism in patients with NVAF.

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New listing (Major Submission)	EDOXABAN Tablet 30 mg Tablet 60 mg Lixiana® Daiichi Sankyo Pty Ltd	Deep vein thrombosis (DVT) and pulmonary embolism (PE) (venous thromboembolism)	To request an Authority Required (STREAMLINED) listing for treatment of DVT and PE.
New listing (Minor Submission)	EPOPROSTENOL Injection 500 microgram Injection 1.5 mg Flolan® GlaxoSmithKline Australia Pty Ltd	Pulmonary arterial hypertension	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a new pH 12 diluent and delisting of the infusion administration set.
Change to listing (Major Submission)	ERIBULIN Solution for I.V. injection containing eribulin mesilate 1 mg in 2 mL Halaven® Eisai Australia Pty Ltd	Soft tissue sarcoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable or metastatic liposarcoma following chemotherapy.

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New listing (Minor Submission)	FLUTICASONE with SALMETEROL Powder for inhalation containing fluticasone propionate 500 micrograms with salmeterol (as xinafoate) 50 micrograms per dose Airflusal Forspiro 500/50 Sandoz Pty Ltd	Asthma and chronic obstructive pulmonary disease (COPD)	To request the Restricted Benefit listing for asthma and chronic obstructive pulmonary disease, with an age restriction of 18 years and older.
New listing (Minor Submission)	FOSAPREPITANT Powder for I.V. infusion 150 mg Emend® IV Merck Sharp & Dohme (Australia) Pty Ltd	Nausea and vomiting	Resubmission to request a General Schedule and Section 100 (Efficient Funding of Chemotherapy - Related Benefits) Authority Required (STREAMLINED) listing of an intravenous formulation of fosaprepitant for the management of nausea and vomiting associated with cytotoxic chemotherapy.
New listing (Minor Submission)	GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS with VITAMINS and MINERALS Sachet containing oral powder 35 g PKU Sphere® Vitaflo Australia Pty Ltd	Phenylketonuria	To request a Restricted Benefit listing for the dietary management of phenylketonuria.

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New listing (Minor Submission)	GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS Sachets containing oral powder 20 g PKU Restore® Cortex Health Pty Ltd	Phenylketonuria	To request a Restricted Benefit for the dietary management of phenylketonuria.
New listing (Minor Submission)	GONADOTROPHIN Powder for injection, 600 I.U Powder for injection, 1200 I.U Menopur® Ferring Pharmaceuticals Pty Ltd	Anovulatory infertility	Resubmission to request a restricted benefit listing for anovulatory infertility.
Change to listing (Minor Submission)	GOSERELIN Implant, 3.6 mg Implant 10.8 mg Zoladex® Implant Medical Oncology Group of Australia	Chemotherapy-induced menopause	To request a Restricted Benefit listing for the prevention of chemotherapy-induced menopause in breast cancer.

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New listing (Minor Submission)	HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW IN PROTEIN and CARBOHYDRATE Oral semi-solid 100 g Keyo® Vitaflo Australia Pty Ltd	Dietary management of conditions requiring a ketogenic diet	To request a Restricted Benefit listing as a dietary supplement for patients requiring a ketogenic diet.
New listing (Major Submission)	IBRUTINIB Capsule 140 mg Imbruvica® Janssen-Cilag Pty Ltd	Relapsed or refractory mantle cell lymphoma	To request an Authority Required listing for the treatment of relapsed or refractory mantle cell lymphoma.
Change to listing (Major Submission)	ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe Firazyr® Shire Australia Pty Ltd	Hereditary angioedema	To request assessment of the cost-effectiveness of icatibant in the context of the current Australian Society of Clinical Immunology and Allergy (ASCIA) treatment algorithm and June 2016 DUSC review.
New listing (Major Submission)	INFLIXIMAB Powder for I.V. infusion 100 mg Renflexis® Merck Sharp & Dohme (Australia) Pty Ltd	Same as currently PBS subsidised indications for infliximab	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a biosimilar infliximab for all indications currently PBS subsidised for infliximab.

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New listing (Major Submission)	IRINOTECAN (NANOLIPOSOMAL) Injection concentrate for I.V. infusion 43 mg in 10 mL Onivyde® Baxalta Australia Pty Ltd	Metastatic pancreatic cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for use in combination with 5-fluorouracil and folinic acid, for the treatment of patients with metastatic pancreatic cancer previously treated with a gemcitabine based regimen.
Change to listing (Major Submission)	IVACAFTOR Sachet containing granules 50 mg Sachet containing granules 75 mg Kalydeco® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) listing of a new form of ivacaftor; and an extension to current ivacaftor listing to include patients aged 2-5 years who have a G551D or other gating (class III) mutation in the CFTR gene.
Change to listing (Major Submission)	LANREOTIDE Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel® Ipsen Pty Ltd	Gastroentero-pancreatic neuroendocrine tumours (GEP-NETs)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of non-functional GEP-NETs in adult patients with un-resectable locally advanced or metastatic disease.

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Change to listing (Major Submission)	LEDIPASVIR with SOFOSBUVIR Tablet containing 90 mg ledipasvir with 400 mg sofosbuvir Harvoni® Gilead Sciences Pty Ltd	Chronic hepatitis C virus (HCV) infection	To request an extension to the General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for ledipasvir with sofosbuvir, for use in combination with ribavirin, for the treatment of patients with HCV genotypes 1 to 6 with decompensated cirrhosis and treatment-naïve patients with HCV genotype 3 with and without cirrhosis.
Change to listing (Minor Submission)	LEVODOPA with CARBIDOPA Intestinal gel containing levodopa 20 mg with carbidopa (as monohydrate) 5 mg in 1 mL Duodopa® Abbvie Pty Ltd	Parkinson disease	To request a change in the Note section of the current Authority Required (STREAMLINED) restriction.
New listing (Minor Submission)	LUMACAFTOR with IVACAFTOR Tablet containing lumacaftor 200 mg with ivacaftor 125 mg Orkambi® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic fibrosis	Resubmission to request a Section 100 (Highly Specialised Drugs Program) 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.

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Change to listing (Minor Submission)	NADROPARIN Injection containing nadroparin calcium (1,900 I.U. anti-Xa) in 0.2 mL (2,850 I.U. anti-Xa) in 0.3 mL (3800 IU anti-Xa) in 0.4 mL (5700 IU anti-Xa) in 0.6 mL (7600 IU anti-Xa) in 0.8 mL (9500 IU anti-Xa) in 1 mL (11400 IU anti-Xa) in 0.6 mL (15200 IU anti-Xa) in 0.8 mL (19000 IU anti-Xa) in 1 mL prefilled syringe Fraxiparine® and Fraxiparine Forte® Aspen Pharmacare Australia Pty Ltd	Deep Vein Thrombosis (DVT) prophylaxis/treatment Haemodialysis	To request an increase in maximum quantities for all strengths of the listed formulations.
Change to listing (Major Submission)	NETUPITANT with PALONOSETRON Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride) Akynzeo® Mundipharma Pty Ltd	Nausea and vomiting associated with emetogenic cancer chemotherapy	Resubmission to request General Schedule and Section 100 (Efficient Funding of Chemotherapy – Related Benefits) Authority Required (STREAMLINED) listings for the treatment of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy.

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Change to listing (Minor Submission)	NILOTINIB Capsule 150 mg (as hydrochloride monohydrate) Capsule 200 mg (as hydrochloride monohydrate) Tasigna® Novartis Pharmaceuticals Australia Pty Ltd	Chronic myeloid leukaemia (CML)	To request the current Authority Required (IN-WRITING) listings for CML be changed to Authority Required (TELEPHONE).
New listing (Major Submission)	NINTEDANIB Capsule 100 mg Capsule 150 mg Ofev® Boehringer Ingelheim Pty Ltd	Idiopathic pulmonary fibrosis (IPF)	Resubmission to request an Authority Required listing for use in patients with IPF.
Change to listing (Major Submission)	NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Squamous non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic squamous NSCLC with progression on or after prior chemotherapy.

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Change to listing (Major Submission)	NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Non-squamous non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic non-squamous NSCLC with progression on or after prior chemotherapy.
New listing (Minor Submission)	NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Renal cell carcinoma (RCC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for second-line clear cell variant renal cell carcinoma.
New listing (Major Submission)	OBINUTUZUMAB Solution for I.V. infusion 1000 mg in 40 mL Gazyva® Roche Products Pty Ltd	Follicular lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as re-induction treatment and maintenance therapy in patients with rituximab-refractory follicular lymphoma.

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Change to listing (Minor Submission)	OMALIZUMAB Injection 150 mg in 1 mL Xolair® Novartis Pharmaceuticals Australia Pty Ltd	Severe chronic idiopathic urticaria	Resubmission to request a re-assessment of the recommended equi-effective dose of omalizumab compared with cyclosporin.
New listing (Minor Submission)	OXYCODONE with NALOXONE Tablet (controlled release) containing oxycodone hydrochloride 80 mg with naloxone hydrochloride 40 mg Tablet (controlled release) containing oxycodone hydrochloride 60 mg with naloxone hydrochloride 30 mg Targin® Mundipharma Pty Ltd	Chronic severe disabling pain	To request an Authority Required listing for two additional strengths of oxycodone with naloxone for the treatment of chronic disabling pain unresponsive to non-opioid analgesics.

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Change to listing (Minor Submission)	OXYCODONE with NALOXONE Tablet (controlled release) containing oxycodone (as hydrochloride) 2.5 mg with naloxone (as hydrochloride)1.25 mg Tablet (controlled release) containing oxycodone (as hydrochloride) 5 mg with naloxone (as hydrochloride)2.5 mg, Tablet (controlled release) containing oxycodone (as hydrochloride) 10 mg with naloxone (as hydrochloride) 5 mg Tablet (controlled release) containing oxycodone (as hydrochloride) 15 mg with naloxone (as hydrochloride) 7.5 mg Tablet (controlled release) containing oxycodone (as hydrochloride) 20 mg with naloxone (as hydrochloride)10 mg Tablet (controlled release) containing oxycodone (as hydrochloride) 30 with naloxone (as hydrochloride) 15 mg Tablet (controlled release) Targin® Mundipharma Pty Ltd	Chronic severe disabling pain	To request the addition of a note to its current Restricted Benefit listing.

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New listing (Major Submission)	PALIPERIDONE I.M. injection (modified release) 175 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 263 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 350 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 525 mg (as palmitate) in pre-filled syringe Invega® Trinza™ Janssen-Cilag Pty Ltd	Schizophrenia	To request an Authority Required (STREAMLINED) listing for the treatment of patients with schizophrenia who have been adequately stabilised with paliperidone modified release injection.
New listing (Major Submission)	PARITAPREVIR with RITONAVIR with OMBITASVIR Tablet containing 75 mg paritaprevir with 50 mg ritonavir with 12.5 mg ombitasvir Technivie® AbbVie Pty Ltd	Chronic hepatitis C virus (HCV) infection	To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for paritaprevir with ritonavir with ombitasvir, in combination with ribavirin, for the treatment of patients with genotype 4 chronic HCV infection.

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New listing (Major Submission)	PEGVISOMANT Powder for injection 10 mg Powder for injection 15 mg Powder for injection 20 mg Somavert® Pfizer Australia Pty Ltd	Acromegaly	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of acromegaly in patients who have had inadequate response to surgery and/or radiation and/or other medical therapies.
New listing (Minor Submission)	PEMBROLIZUMAB Powder for injection 100 mg Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Melanoma	To request a Section 100 (Efficient funding of Chemotherapy) Authority Required (STREAMLINED) listing of an additional strength of pembrolizumab for unresectable stage III or stage IV malignant melanoma
Change to listing (Major Submission)	PEMBROLIZUMAB Powder for injection 50 mg Keytruda® Merck Sharp and Dohme (Australia) Pty Ltd	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of PD-L1 positive NSCLC in patients refractory to platinum based chemotherapy.
Change to listing (Major Submission)	PEMBROLIZUMAB Powder for injection 50 mg Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Melanoma	Resubmission to seek PBAC reconsideration of the cost-effectiveness of pembrolizumab for the treatment of unresectable stage III or stage IV metastatic melanoma.

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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 (Major Submission)	PIRFENIDONE Capsule 267 mg Esbriet® Roche Products Pty Ltd	Idiopathic pulmonary fibrosis (IPF)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of IPF.
New listing (Major Submission)	ROMIDEPSIN Powder for I.V. infusion 10 mg Istodax® Rare Cancers Australia	Relapsed or refractory peripheral T-cell lymphoma	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of relapsed or chemotherapy refractory peripheral T-cell lymphoma.
Change to listing (Minor Submission)	SALBUTAMOL Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 20 Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd	Asthma	To request a change to the pack size.

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New listing (Major Submission)	SOFOSBUVIR with VELPATASVIR Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir Epclusa® Gilead Sciences Pty Ltd	Chronic hepatitis C virus (HCV) infection	To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for the treatment of chronic HCV infection, regardless of genotype. For patients with decompensated liver disease, the requested listing is in combination with ribavirin.
Change to listing (Minor Submission)	SOMATROPIN Injection 6 mg (18 i.u.) in 1.03 mL 12 mg (36 i.u.) in 1.5 mL 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative) Saizen® Merck Serono Australia Pty Ltd	Severe growth hormone deficiency	To request an Authority Required listing for the treatment of growth disturbance (growth retardation) in pre-pubertal children due to chronic renal insufficiency (CRI).
Change to listing (Major Submission)	SOMATROPIN All forms and strengths All brands Endocrine Society of Australia; Australian Paediatric Endocrine Group	Severe growth hormone deficiency	Resubmission to request a Section 100 (Growth Hormone) Authority Required listing for the treatment of adults with severe growth hormone deficiency and substantially impaired quality of life at baseline.

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Change to listing (Minor Submission)	TERIFLUNOMIDE Tablet 14 mg Aubagio® Sanofi-aventis Australia Pty Ltd	Multiple sclerosis	To request the current Authority Required listing be changed to Authority Required (STREAMLINED).
Change to listing (Minor Submission)	TIOTROPIUM with OLODATEROL Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses Spiolto® Respimat® Boehringer Ingelheim Pty Ltd	Chronic obstructive pulmonary disease (COPD)	To request a change to the current Authority Required (STREAMLINED) listing for tiotropium with olodaterol to include patients who have persistent COPD symptoms despite regular monotherapy with a long-acting muscarinic antagonist or a long-acting beta-2 agonist.
Change to recommended listing (Minor Submission)	TOCILIZUMAB Injection 162 mg in 0.9 mL Actemra® Roche Products Pty Ltd	Rheumatoid arthritis	Resubmission to request a revision of the March 2016 PBAC recommendation.

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New listing (Major Submission)	TOLVAPTAN Tablet 15 mg Tablet 30 mg Pack containing 28 tablets 15 mg and 28 tablets 45 mg Pack containing 28 tablets 30 mg and 28 tablets 60 mg Pack containing 28 tablets 30 mg and 28 tablets 90 mg Jinarc® Otsuka Australia Pharmaceutical Pty Ltd	Autosomal dominant polycystic kidney disease (ADPKD)	To request an Authority Required listing for the treatment of ADPKD.
New listing (Major Submission)	TRIFLURIDINE with TIPIRACIL Tablet containing 15 mg trifluridine with 6.14 mg tipiracil Tablet containing 20 mg trifluridine with 8.19 mg tipiracil Lonsurf® Servier Laboratories (Australia) Pty Ltd	Metastatic colorectal cancer	To request an Authority Required (STREAMLINED) listing for the treatment of metastatic colorectal cancer.

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New listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN and LONG CHAIN with GLUCOSE POLYMER Sachet containing oral powder 21 g Sachet containing oral powder 31 g Sachet containing oral powder 42 g Sachet containing oral powder 52 g SOS10®, SOS15®, SOS20®, SOS25® Vitaflo Australia Pty Ltd	Dietary management of proven inborn errors of protein or fat metabolism	To request a Restricted Benefit listing for proven inborn errors of protein or fat metabolism.
New listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral liquid solution, 500mL Nutrini Peptisorb Energy Nutricia Australia Pty Ltd	Dietary management of conditions requiring a source of medium chain triglycerides	To request a Restricted Benefit listing for dietary management of conditions requiring a source of medium chain triglycerides.
Change to listing (Minor Submission)	VARENICLINE Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack Tablet 1 mg (as tartrate) Champix® Pfizer Australia Pty Ltd	Nicotine dependence	To request the current Authority Required listing be changed to Authority Required (STREAMLINED).

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Change to recommended listing (Minor Submission)	VISMODEGIB Capsule 150 mg Erivedge® Roche Products Pty Ltd	Metastatic or locally advanced basal cell carcinoma (BCC)	Resubmission to supply new clinical information in relation to the March 2016 PBAC recommendation of vismodegib for the treatment of metastatic or locally advanced BCC.
Change to listing (Minor Submission)	VITAMIN, MINERAL, AND TRACE ELEMENTS with CARBOHYDRATE Sachet 6 g Fruitivits® Vitaflo Australia Pty Ltd	Dietary management of conditions requiring a highly restrictive therapeutic diet	To request a change to the restriction to include children aged 1 year or older.
New listing (Major Submission)	VORINOSTAT Capsule 100 mg Zolinza® Rare Cancers Australia	Relapsed or refractory cutaneous T-cell lymphoma	Resubmission to request an Authority Required listing for the treatment of relapsed or chemotherapy refractory cutaneous T-cell lymphoma.
New listing (Minor Submission)	WARFARIN Tablet containing warfarin sodium, 1 mg Tablet containing warfarin sodium, 2 mg Tablet containing warfarin sodium, 5 mg Warfarin APOTEX® Apotex Pty Ltd	Unrestricted	To request the listing of a new brand of warfarin (Warfarin APOTEX®) with an 'a-flag' to a currently listed brand of warfarin (Coumadin®).

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Sub-committee report (DUSC Analysis)	Posaconazole Voriconazole Fluconazole Itraconazole Terbinafine Griseofulvin Ketoconazole (all current and previously listed brands including generic versions)	Antifungals	To assess the use of PBS listed antifungal medicines, including the comparison of the predicted and actual use of voriconazole since the addition of an Authority Required listing for prophylaxis of fungal infections in certain high risk patients.
Sub-committee report (DUSC Analysis)	Quetiapine Amisulpride Aripiprazole Asenapine Clozapine Lurasidone Olanzapine Paliperidone Ziprasidone Risperidone Lithium (all current and previously listed brands including generic versions)	Antipsychotics	To assess the use of PBS listed antipsychotic medicines, including the comparison of the predicted and actual use of 25 mg quetiapine after the restriction was altered to remove repeats from PBS prescriptions.
Sub-committee report (DUSC Analysis)	Mifepristone and misoprostol MS 2 Step®	Termination of intra-uterine pregnancies	To compare the predicted and actual use of PBS listed mifepristone and misoprostol.

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Sub-committee report (DUSC Analysis)	Denosumab Alendronate Clodronate Risedronate Zoledronic acid Calcitriol Raloxifene Teriparatide Alendronate + Colecalciferol Alendronate & Colecalciferol + Calcium Risedronate & Calcium Risedronate & Calcium + Colecalciferol (all current and previously listed brands including generic versions)	Osteoporosis	To assess the use of the medicines PBS listed to treat osteoporosis, including the comparison of the predicted and actual use of denosumab.
Sub-committee report (DUSC Analysis)	Rifaximin Xifaxan®	Hepatic encephalopathy	To compare the predicted and actual use of rifaximin.
Sub-committee report (DUSC Analysis)	Testosterone Testosterone enanthate Testosterone undecanoate (all current and previously listed brands including generic versions)	Androgen deficiency	To examine the use of PBS listed testosterone to assess the impact of the change in restriction that occurred 1 April 2015.