PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2017 PBAC MEETING

Closing date for consumer comments 7 June 2017

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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New listing (Minor Submission)	ABIRATERONE Tablet containing abiraterone acetate 500 mg Zytiga® Janssen-Cilag Pty Ltd	Castration resistant metastatic carcinoma of the prostate	To request an Authority Required listing of a new form of abiraterone.
New listing (Minor Submission)	ADALIMUMAB Injection 40 mg in 0.8mL vial Humira® Abbvie Pty Ltd	Same as currently PBS subsidised indications for adalimumab	To request an Authority Required General Schedule and Section 100 (Highly Specialised Drug) listing for a new form of adalimumab.
New listing (Major Submission)	ALECTINIB Capsule 150 mg Alecensa® Roche Products Pty Ltd	Non-small cell lung cancer (NSCLC)	To request an Authority Required listing for the treatment of patients with locally advanced or metastatic NSCLC under certain conditions.

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New listing (Minor Submission)	AMINO ACID FORMULA supplemented with PREBIOTICS, PROBIOTICS and LONG CHAIN POLYUNSATURATED FATTY ACIDS Oral powder, 400 g (Neocate Syneo) Neocate® Syneo™ Nutricia Australia Pty Ltd	Cows' milk protein enteropathy Severe cows' milk protein enteropathy with failure to thrive Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Cows' milk anaphylaxis Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Severe intestinal malabsorption including short bowel syndrome Eosinophilic oesophagitis	To request an Authority Required listing for infants (up to 24 months) for the treatment of cows' milk protein enteropathy; severe cows' milk protein enteropathy with failure to thrive; combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae; proven combined immunoglobulin E mediated allergy to cows' milk protein and soy protein; eosinophilic eosophagitis; cows' milk anaphylaxis; and severe intestinal malabsorption including short bowel syndrome.
New listing (Minor Submission)	AMINO ACID FORMULA with CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS WITHOUT PHENYLALANINE, SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID Sachets containing oral powder 33 g, 30 (PKU Synergy)PKU Synergy® Nutricia Australia Pty Ltd	Phenylketonuria	To request a Restricted Benefit listing of PKU Synergy for the dietary management of patients with phenylketonuria.

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Closing date for consumer comments 7 June 2017

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New listing (Minor Submission)	AMINO ACID FORMULA with VITAMINS and MINERALS WITHOUT PHENYLALANINE Oral liquid 125 mL, 30 (PKU Lophlex LQ 20) Sachets containing oral powder 27.8 g, 30 (Lophlex) PKU Lophlex® LQ 20 Lophlex® Nutricia Australia Pty Ltd	Phenylketonuria	To request Restricted Benefit listings of two forms of amino acid based formulations for the treatment of patients with phenylketonuria.
Change to listing (Minor Submission)	ANAKINRA Injection 100 mg in 0.67 mL single use pre-filled syringe Kineret® A.Menarini Australia Pty Ltd	Moderate to severe cryopyrin associated periodic syndromes	To request the current Authority Required (STREAMLINED) listing be changed to Authority Required.
New listing (Major Submission)	ASFOTASE ALFA Injection 18 mg in 0.45 mL, vial Injection 28 mg in 0.7 mL, vial Injection 40 mg in 1 mL, vial Injection 80 mg in 0.8 mL, vial Strensiq® Alexion Pharmaceuticals Australasia Pty Ltd	Hypophosphatasia (HPP)	To request a Section 100 (Highly Specialised Drugs Program) listing for the treatment of patients with paediatric-onset HPP who meet certain conditions.

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Closing date for consumer comments 7 June 2017

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New listing (Minor Submission)	BACLOFEN Intrathecal injection 40 mg in 20 mL Sintetica Baclofen Intrathecal® Boucher & Muir Pty Ltd	Severe chronic spasticity	To request a Section 100 (Highly Specialised Drugs Program) listing of a new form of baclofen.
New listing (Minor Submission)	BALSALAZIDE Capsule containing balsalazide sodium 750 mg Colazide® Fresenius Kabi Australia Pty Ltd	Ulcerative colitis	To request a new maximum quantity for the current Authority Required (Streamlined) listing.
New listing (Major Submission)	BARICITINIB Tablet 2 mg Tablet 4 mg Olumiant® Eli Lilly Australia Pty Ltd	Severe active rheumatoid arthritis	To request an Authority Required listing for the treatment of severe active rheumatoid arthritis under certain conditions.

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Change to listing (Minor Submission)	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX Lyophilised powder for injection 100 units Botox® CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX Lyophilised powder for I.M. injection 300 units Dysport® INCOBOTULINUMTOXINA Lyophilised powder for injection 100 units Xeomin® Rehabilitation Medicine Society of Australia and New Zealand	Dynamic equinus foot deformity and moderate to severe spasticity of the upper limb	To request a change to the current restrictions to remove the requirement that adult cerebral palsy patients must have commenced treatment with any of the three forms of Botulinum Toxin Type A as a paediatric patient and remove the limitation of 4 treatment periods per upper limb per lifetime.
New listing (Minor Submission)	BUDESONIDE with EFORMOTEROL Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with eformoterol fumarate dihydrate 6 micrograms per dose, 120 doses Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with eformoterol fumarate dihydrate 12 micrograms per dose, 120 doses DuoResp® Spiromax Teva Pharma Australia Pty Ltd	Asthma and chronic obstructive pulmonary disease (COPD)	To request a Restricted Benefit listing for a new brand of budesonide with eformoterol (DuoResp® Spiromax) for the treatment of patients with asthma and COPD aged 18 years and over.

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Closing date for consumer comments 7 June 2017

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New listing (Major Submission)	BUDESONIDE Tablet 9 mg Cortiment® Ferring Pharmaceuticals Pty Ltd	Unrestricted	To request an unrestricted listing. The main indication for which listing is sought is for the treatment of patients with mild to moderate active ulcerative colitis.
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	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for carfilzomib in combination with dexamethasone for the treatment of patients with multiple myeloma who have failed at least one prior line of treatment.
Change to listing (Minor Submission)	DAPAGLIFLOZIN with METFORMIN Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride Xigduo® XR AstraZeneca Pty Ltd	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing of dapagliflozin with metformin for the treatment of T2DM in combination with a dipeptidyl peptidase 4 inhibitor.

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JULY 2017 PBAC MEETING

Closing date for consumer comments 7 June 2017

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Change to listing (Major Submission)	DAPAGLIFLOZIN Tablet 10 mg (as propanediol monohydrate) Forxiga® AstraZeneca Pty Ltd	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for dapagliflozin in combination with metformin and a dipeptidyl peptidase 4 inhibitor for the treatment of patients with T2DM.
New listing (Minor Submission)	DOCETAXEL Solution concentrate for I.V. infusion 160 mg in 8 mL Docetaxel Accord® Accord Healthcare Pty. Ltd.	Unrestricted	To request an unrestricted listing for a new form of docetaxel.
Change to listing (Minor Submission)	ECULIZUMAB Solution concentrate for I.V. infusion 300 mg in 30 mL Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	Atypical haemolytic uraemic syndrome (aHUS) in end stage renal disease (ESRD)	Resubmission to request an extension to the Authority Required listing for the treatment of patients with aHUS in ESRD who are eligible for a renal transplant.
Change to listing (Minor Submission)	ENZALUTAMIDE Capsule 40 mg Xtandi® Astellas Pharma Australia Pty Ltd	Prostate cancer	Resubmission to request an Authority Required listing for the treatment of asymptomatic metastatic castration resistant prostate cancer in chemotherapy-naïve patients.

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JULY 2017 PBAC MEETING

Closing date for consumer comments 7 June 2017

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Change to listing (Minor Submission)	EPOETIN LAMBDA Injection 1,000 units in 0.5 mL pre-filled syringe Injection 2,000 units in 1 mL pre-filled syringe Injection 3,000 units in 0.3 mL pre-filled syringe Injection 4,000 units in 0.4 mL pre-filled syringe Injection 5,000 units in 0.5 mL pre-filled syringe Injection 6,000 units in 0.6 mL pre-filled syringe Injection 8,000 units in 0.8 mL pre-filled syringe Injection 10,000 units in 1 mL pre-filled syringe Novicrit® Sandoz Pty Ltd.	Anaemia associated with intrinsic renal disease	To request removal of the NOTE in the restriction limiting epoetin lambda to the intravenous route.
Change to recommended listing (Minor Submission) WITHDRAWN	ERIBULIN Solution for I.V. injection containing eribulin mesilate 1 mg in 2 mL Halaven® Eisai Australia Pty Ltd	Soft tissue sarcoma	To supply new clinical information in relation the November 2016 PBAC recommendation, for eribulin for the treatment of unresectable or metastatic liposarcoma following chemotherapy.

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Change to listing (Major Submission) WITHDRAWN	EVEROLIMUS Tablet 2 mg, dispersible Tablet 3 mg, dispersible Tablet 5 mg, dispersible Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Tuberous sclerosis complex	To request an Authority Required listing for the treatment of patients with refractory seizures associated with tuberous sclerosis complex in combination with other anti-epileptic medications.
New listing (Minor Submission)	EVOLOCUMAB Injection 420 mg in 3.5 mL single dose autoinjector Repatha® Amgen Australia Pty Ltd	Familial homozygous hypercholesterolaemia	To request an Authority Required listing for a new form of evolocumab.
Change to listing (Minor Submission)	FEBUXOSTAT Tablet 80 mg Adenuric® A.Menarini Australia Pty Ltd	Chronic gout	To request the current Authority Required listing be changed to Authority Required (STREAMLINED).

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JULY 2017 PBAC MEETING

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Change to listing (Minor Submission)	FENTANYL Tablet (sublingual) 100 micrograms (as citrate) Tablet (sublingual) 200 micrograms (as citrate) Abstral® A.Menarini Australia Pty Ltd	Breakthrough pain	To request an increase to the maximum quantity packs per authority script for breakthrough pain to two packs for initial treatment, to facilitate complete dose titration in patients receiving palliative care.
Change to listing (Major Submission)	GLATIRAMER Injection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled syringe Copaxone® Teva Pharma Australia Pty Ltd	Clinically isolated syndrome (CIS)	To request an Authority Required (STREAMLINED) listing for the treatment of patients with CIS under certain conditions.
New listing (Major Submission)	GLECAPREVIR with PIBRENTASVIR Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir Trade name to be determined Abbvie Pty Ltd	Chronic hepatitis C virus (HCV) infection	To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings for the treatment of chronic HCV infection, regardless of genotype.

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Closing date for consumer comments 7 June 2017

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New listing (Minor Submission)	GLYCOMACROPEPTIDE FORMULA with LONG CHAIN POLYUNSATURATED FATTY ACIDS and DOCOSAHEXAENOIC ACID and LOW IN PHENYLALANINE Sachets containing oral powder 27 g, 30 (PKU Sphere 15) Sachets containing oral powder 35 g, 30 (PKU Sphere 20) PKU Sphere® 15 PKU Sphere® 20 Vitaflo Australia Pty Ltd	Phenylketonuria	To request a name change to the current PBS listed 'PKU Sphere' and request a Restricted Benefit listing of a new form of glycomacropeptide formula (PKU Sphere15).
New listing (Major Submission)	GUANFACINE Tablet containing guanfacine hydrochloride 1 mg Tablet containing guanfacine hydrochloride 2 mg Tablet containing guanfacine hydrochloride 3 mg Tablet containing guanfacine hydrochloride 4 mg Intuniv® Shire Australia Pty Ltd	Attention deficit hyperactivity disorder (ADHD)	To request an Authority Required listing of guanfacine for the treatment of ADHD in patients aged 6-18 years who are contraindicated to or have withdrawn from dexamfetamine, methylphenidate or lisdexamfetamine therapy; or as add-on therapy following an unsatisfactory response to optimised stimulant therapy.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2017 PBAC MEETING

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New listing (Major Submission)	HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE Injection 0.5 mL, pre-filled syringe Gardasil® 9 Seqirus (Australia) Pty Ltd	Prevention of human papilloma virus (HPV)	To request listing on the National Immunisation Program as a 2-dose schedule for females and males aged 12-13 years as part of a school age program for the prevention of HPV to replace the current 3-dose schedule of 4-valent HPV vaccine.
Change to listing (Minor Submission)	ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe Firazyr® Shire Australia Pty Ltd	Hereditary angioedema	To request a change to the current Authority Required listing to limit any authorised increase in the maximum quantity to 12 per script.
Change to listing (Major Submission)	LANREOTIDE Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel® Ipsen Pty Ltd	Non-functional 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.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2017 PBAC MEETING

Closing date for consumer comments 7 June 2017

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New listing (Major Submission)	LIRAGLUTIDE Injection 6 mg/mL, 3 mL pre-filled pen Victoza® Novo Nordisk Pharmaceuticals Pty Ltd	Type 2 diabetes mellitus (T2DM)	Resubmission to request an Authority Required (STREAMLINED) listing in combination with metformin and/or a sulfonylurea, or insulin, for the treatment of patients with T2DM under certain conditions.
New listing (Major 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 over who are homozygous for the F508del mutation in the CFTR gene.
Change to listing (Major Submission)	MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers Bronchitol® Pharmaxis Ltd	Cystic fibrosis	Resubmission to request a change to the current listing to allow for treatment in combination with dornase alfa in patients who are inadequately responsive to dornase alfa.
New listing (Major Submission)	METHOXSALEN Solution for blood fraction, 20 microgram per mL, 10 mL Uvadex® Terumo BCT Australia Pty Ltd	Erythrodermic cutaneous T-cell lymphoma	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of patients with advanced stage, erythrodermic cutaneous T-cell lymphoma under certain conditions, as part of treatment with integrated, closed system, extracorporeal photopheresis.

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JULY 2017 PBAC MEETING

Closing date for consumer comments 7 June 2017

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New listing (Minor Submission)	MIGALASTAT Capsule containing migalastat hydrochloride 150 mg Galafold® Amicus Therapeutics	Fabry disease	Resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required listing for the treatment of Fabry disease.
New listing (Major Submission)	NICOTINE Gum 2 mg Gum 4 mg Lozenge 2 mg Lozenge 4 mg Nicotinell Chewing gum® Nicotinell lozenge® Orion Laboratories Pty Ltd T/A Perrigo Australia	Nicotine dependence	To request a Restricted Benefit listing for nicotine chewing gum and lozenges to aid smoking cessation in patients with nicotine dependence.
New listing (Major Submission)	OCRELIZUMAB Solution concentrate for I.V. infusion 300 mg in 10 mL Ocrevus® Roche Products Pty Ltd	Relapsing-remitting multiple sclerosis (RRMS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of RRMS.

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Change to listing (Minor Submission)	PEGFILGRASTIM Injection 6 mg in 0.6 mL single use pre-filled syringe Neulasta® Ristempa® Amgen Australia Pty Ltd	Prophylaxis of chemotherapy induced neutropenia	To request a Section 100 (Highly Specialised Drug) Authority Required listing for the treatment of patients for primary prophylaxis of chemotherapy induced neutropenia in patients with early stage breast cancer in patients receiving docetaxel and cyclophosphamide based chemotherapy.
Change to listing (Major Submission)	PEMBROLIZUMAB Powder for injection 50 mg Solution for I.V. infusion 100 mg in 4 mL Keytruda® Merck, Sharp and Dohme (Australia) Pty Ltd	Classical Hodgkin's lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with refractory classical Hodgkin’s lymphoma, or those who have relapsed after 3 or more prior lines of therapy.
Change to listing (Major Submission)	PERAMPANEL Tablet 2 mg (as hemisesquihydrate) Tablet 4 mg (as hemisesquihydrate) Tablet 6 mg (as hemisesquihydrate) Tablet 8 mg (as hemisesquihydrate) Tablet 10 mg (as hemisesquihydrate) Tablet 12 mg (as hemisesquihydrate) Fycompa® Eisai Australia Pty Ltd	Epilepsy	Resubmission to request an Authority Required (STREAMLINED) listing for perampanel for the treatment of idiopathic generalised epilepsy with primary generalised tonic-clonic seizures under certain conditions.

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New listing (Major Submission)	PRALATREXATE Solution for I.V. infusion 20 mg in 1 mL Folotyn® Mundipharma Pty Ltd	Peripheral T-cell lymphoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with peripheral T-cell lymphoma who are refractory to, or have relapsed following, first line chemotherapy.
New listing (Minor Submission)	PROPRANOLOL Oral liquid, 3.75 mg per mL, 120 mL Hemangiol® Pierre Fabre Medicament Australia Pty Ltd	Infantile haemangioma	Resubmission to request an Authority Required listing for the treatment of proliferating infantile hemangioma requiring systemic therapy.
New listing (Major Submission)	RALTEGRAVIR Tablet 600 mg (as potassium) Isentress HD® Merck, Sharp and Dohme (Australia) Pty Ltd	Human immunodeficiency virus (HIV) infection	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection in combination with other antiretroviral agents.
New listing (Major Submission)	RIBOCICLIB Tablet 200 mg Kisqali® Novartis Pharmaceuticals Australia Pty Ltd	Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer	To request an Authority Required listing for ribociclib in combination with letrozole for the treatment of patients with HR+, HER2- advanced or metastatic breast cancer who are not premenopausal.

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Change to listing (Minor Submission)	RITUXIMAB Solution for subcutaneous injection containing rituximab 1400 mg in 11.7 mL Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL Mabthera® SC Mabthera® Roche Products Pty Ltd	CD20 positive lymphoma	To consider the available evidence for the consolidation of all existing listings of rituximab for CD20 positive lymphomas.
New listing (Minor Submission) WITHDRAWN	ROMIDEPSIN Powder for I.V. infusion 10 mg Istodax® Celgene Pty Ltd	Relapsed or refractory peripheral T-cell lymphoma	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of relapsed or refractory peripheral T-cell lymphoma. The original submission was made by Rare Cancers Australia.
New listing (Major Submission)	SAXAGLIPTIN with DAPAGLIFLOZIN Tablet containing saxagliptin 5 mg with dapaglifozin 10 mg Qtern® AstraZeneca Pty Ltd	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for dapagliflozin with saxagliptin in combination with metformin for the treatment of T2DM.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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Change to listing (Minor Submission)	SECUKINUMAB Injection 150 mg in 1 mL pre-filled pen Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd	Severe chronic plaque psoriasis	To request a change in the maximum quantity of packs per script for severe chronic plaque psoriasis continuing treatment to provide 8 weeks of treatment.
New listing (Major Submission) WITHDRAWN	SODIUM CHLORIDE Nebuliser solution 30 mg per mL (3%), 4 mL ampoule Nebuliser solution 60 mg per mL (6%), 4 mL ampoule Mucoclear® 3% Mucoclear® 6% Technipro PulmoMed Pty Ltd	Unrestricted	To request an unrestricted listing. The main indication for which listing is sought is to increase the mobilisation of secretions in the lower respiratory tract in cystic fibrosis patients with persistent mucous accumulation by osmotic effects.
Change to recommended listing (Minor 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 that the PBAC review its advice that sofosbuvir with velpatasvir should be treated as interchangeable on an individual patient basis with other direct-acting antiviral regimens under Section 101(3BA) of the *National Health Act 1953*.

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Change to listing (Minor 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.
Change to listing (Minor Submission)	TENOFOVIR with EMTRICITABINE Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg Tenofovir Disoproxil Emtricitabine Mylan 300/200® Alphapharm Pty Ltd (trading as Mylan Australia)	Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP)	To request an Authority Required (STREAMLINED) listing for PrEP in adults at high risk of HIV infection.
Change to listing (Major Submission)	TENOFOVIR with EMTRICITABINE Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg Truvada® Gilead Sciences Pty Ltd	Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP)	Resubmission to request an Authority Required (STREAMLINED) listing for PrEP in adults at medium to high risk of HIV infection.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2017 PBAC MEETING

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Change to listing (Minor Submission)	TIOTROPIUM Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) Spiriva® Respimat® Boehringer Ingelheim Pty Ltd	Severe asthma	To request the current Restricted Benefit listing to be changed to Authority Required (STREAMLINED).
New listing (Minor Submission)	TRIFLURIDINE WITH TIPIRACIL Tablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride) Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride) Lonsurf® Servier Laboratories (Australia) Pty Ltd	Metastatic colorectal cancer	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of metastatic colorectal cancer.
Change to listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral powder 400 g (Monogen) Monogen® Nutricia Australia Pty Ltd	Dietary management of conditions requiring a source of medium chain triglycerides	To advise the PBAC of a change to the formulation of Monogen.

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New listing (Minor Submission)	VENETOCLAX Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd	Relapsed/refractory chronic lymphoid leukaemia (CLL)	Resubmission to request an Authority Required listing for the treatment of relapsed/refractory CLL.
New listing (Major Submission)	VINFLUNINE Solution concentrate (as ditartrate) for I.V. infusion 50 mg in 2 mL Solution concentrate (as ditartrate) for I.V. infusion 250 mg in 10mL Javlor® Pierre Fabre Medicament Australia Pty Ltd	Transitional cell carcinoma of the urothelial tract	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of locally advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen.
New listing (Minor Submission)	VITAMINS, MINERALS and TRACE ELEMENTS FORMULA Sachets containing oral powder 7 g, 30 (Phlexy Vits) Phlexy Vits® Nutricia Australia Pty Ltd	Dietary management of conditions requiring a highly restrictive therapeutic diet	To request a Restricted Benefit listing of Phlexy Vits for patients requiring a highly restrictive therapeutic diet who have been unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

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Sub-committee report (DUSC analysis)	DUSC Analysis - Botulinum toxin type A Botox® Allergan Australia Pty Ltd	Chronic migraine	To compare the predicted and actual utilisation of the Botulinum toxin type A (Botox®) for chronic migraine in adults since it was listed for this indication in March 2014.
Sub-committee report (DUSC analysis)	DUSC Analysis - Crohn disease Remicade® Inflectra® Humira® Entyvio® Janssen-Cilag Pty Ltd Pfizer Australia Pty Ltd Abbvie Pty Ltd Takeda Pharmaceuticals Australia Pty Ltd	Crohn disease	To report on the use of PBS-listed biologics to treat Crohn disease.
Sub-committee report (DUSC analysis)	DUSC Analysis - Tobramycin inhalation powder TOBI podhaler® Novartis Pharmaceuticals Australia Pty Ltd	Cystic fibrosis	To report on the use of PBS-listed tobramycin inhalation powder for pseudomonas aeruginosa infection in cystic fibrosis patients, including an assessment of the predicted versus actual use.
Sub-committee report (DUSC analysis)	DUSC Analysis - ulcerative colitis (all current and previously listed brands)	Ulcerative colitis	To analyse the use of medicines for the treatment of ulcerative colitis.

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Post market review report	EZETIMIBE EZETIMIBE with SIMVASTATIN EZETIMIBE with ATORVASTATIN ROSUVASTATIN with EZETIMIBE Various strengths Ezetrol® Vytorin® Atozet® Rosuzet composite pack® Merck, Sharp and Dohme (Australia) Pty Ltd	High cholesterol	To consider the findings of the final report for the Post market review of ezetimibe.
Other business	ATAGI review into 23-valent pneumococcal polysaccharide vaccine (23vPPV) 0.5 mL injection Pneumovax 23® Australian Technical Advisory Group on Immunisation	Prevention of pneumococcal disease	To request consideration of ATAGI's review into the use of 23vPPV on the National Immunisation Program schedule, as requested by the PBAC in its consideration of 13-valent pneumococcal conjugate vaccine at its July 2016 meeting.
Other business	ATAGI review into pertussis vaccinations dTpa vaccine, 0.5 mL injection Boostrix®, Adacel® Australian Technical Advisory Group on Immunisation	Prevention of pertussis	To request consideration of ATAGI's review of pertussis vaccinations (with a particular focus on the booster doses administered in pre-school and adolescence) on the National Immunisation Program schedule, as requested by the PBAC in its consideration of dTpa vaccination during pregnancy at its July 2016 meeting.