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

Closing date for consumer comments 8 February 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.

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

Closing date for consumer comments 8 February 2017

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.)
Change to listing (Major Submission)	ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Humira® AbbVie Pty Ltd	Non-infectious intermediate, posterior or panuveitis uveitis (inflammatory disease of the eye)	To request an Authority Required listing for the treatment of vision threatening non-infectious intermediate, posterior or panuveitis uveitis.
New listing (Minor Submission)	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES Oral powder 400 g Neocate Junior® Nutricia Australia Pty Ltd	The dietary management of conditions involving gastrointestinal tract impairment	To request an Authority Required listing of a drug 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.
Change to listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Oral liquid 130 mL, 30 Oral liquid 174 mL, 30 PKU Air® Vitaflo Australia Pty Ltd	Phenylketonuria	To request changes to the Restricted Benefit listing of PKU Air including nutritional content and to add an additional flavour.

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

Closing date for consumer comments 8 February 2017

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.)
Change to listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Oral liquid 87 mL, 30 Oral liquid 130 mL, 30 Oral liquid 174 mL, 30 PKU Cooler® Vitaflo Australia Pty Ltd	Phenylketonuria	To request changes to the Restricted Benefit listing of PKU Cooler including nutritional content and to add an additional flavour.
New listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE Sachets containing oral powder 34 g, 30 TYR Express20® Vitaflo Australia Pty Ltd	Tyrosinaemia	To request a Restricted Benefit listing of a new sachet size containing 20 g protein equivalent for the dietary management of tyrosinaemia.
New listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID Sachets containing oral powder 12.5 g, 30 PKU Anamix First Spoon® Nutricia Australia Pty Ltd	Phenylketonuria	To request a Restricted Benefit listing for phenylketonuria.

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

Closing date for consumer comments 8 February 2017

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.)
Resubmission (Minor Submission)	APREMILAST Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg Otezla® Celgene Pty Ltd	Moderate to severe plaque psoriasis	Resubmission to request an Authority Required (STREAMLINED) listing for treatment of patients with moderate to severe plaque psoriasis.
Change to listing (Minor Submission)	BOTULINUM TOXIN TYPE A Lyophilised powder for injection 100 units Botox® Allergan Australia Pty Ltd	Urinary incontinence due to idiopathic overactive bladder	To request a change to listing to include prescribing by gynaecologists.
New listing (Major Submission)	BREXIPIPRAZOLE Tablet 1 mg Tablet 2 mg Tablet 3 mg Tablet 4 mg Rexulti® Lundbeck Australia Pty Ltd	Schizophrenia	To request an Authority Required (STREAMLINED) listing for the treatment of schizophrenia.

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

Closing date for consumer comments 8 February 2017

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)	BRIVARACETAM Tablet 25 mg Table 50 mg Tablet 75 mg Tablet 100 mg Oral suspension 10 mg per mL, 300 mL Briviact® UCB Australia Pty Ltd	Epilepsy	Resubmission to request an Authority Required (STREAMLINED) listing for treatment of partial epileptic seizures.
New listing (Minor Submission)	CERTOLIZUMAB Injection 200 mg in 1 mL single dose auto-injector Cimzia® UCB Australia Pty Ltd	Severe active rheumatoid arthritis, severe psoriatic arthritis, and active ankylosing spondylitis	To request an Authority Required listing of a new formulation for the treatment of severe active rheumatoid arthritis, severe psoriatic arthritis and active ankylosing spondylitis.
New listing (Minor Submission)	CHORIONIC GONADOTROPIN Injection set containing 3 vials powder for injection 1,500 units and 3 vials diluent 1 mL Injection set containing 1 vial powder for injection 5,000 units and 1 vial dileunt 1 mL Pregnyl® Merck Sharp & Dohme (Australia) Pty Ltd	Anovulatory infertility, infertility, combined deficiency of human growth hormone and gonadotrophins, hypogonadism or delayed puberty, and assisted reproductive technology	To request a Restricted Benefit listing of a new form of chorionic gonadotrophin for the currently listed indication.

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

Closing date for consumer comments 8 February 2017

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.)
Change to listing (Minor Submission)	CRIZOTINIB Capsule 200 mg Capsule 250 mg Xalkori® Pfizer Australia Pty Ltd	Non-small cell lung cancer	To inform the PBAC of the outcome of the Managed Entry Scheme (MES) for crizotinib and to request changes to the restriction to remove the need for oncologists to register patients for the MES and to remove the grandfather restriction.
Change to listing (Minor Submission)	DEGARELIX Powder for injection 80 mg (as acetate), injection set Powder for injection 120 mg (as acetate), injection set Firmagon® Ferring Pharmaceuticals Pty Ltd	Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate	To request that the Authority Required (STREAMLINED) listing be changed to a Restricted Benefit listing to be consistent with other listed gonadotropin-releasing hormone (GnRH) analogues.
Change to listing (Major Submission)	dTpa VACCINE Injection 0.5 mL Adacel® Sanofi-Aventis Australia Pty Ltd	Prevention of pertussis	National Immunisation Program (NIP) listing for all women in every pregnancy, primarily to reduce the risk of pertussis in newborn infants up to 2 months of age.

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

Closing date for consumer comments 8 February 2017

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)	EMPAGLIFLOZIN WITH LINAGLIPTIN Tablet containing 10 mg empagliflozin with 5 mg linagliptin Tablet containing 25 mg empagliflozin with 5 mg linagliptin Glyxambi® Boehringer Ingelheim Pty Ltd	Type 2 diabetes	To request an Authority Required (STREAMLINED) listing for use as add-on therapy to metformin for the treatment of diabetes mellitus type 2.
Change to listing (Major 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.
New listing (Major Submission)	FLUTICASONE FUROATE Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms per dose Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms per dose Arnuity Ellipta® GlaxoSmithKline Australia Pty Ltd	Asthma	Resubmission to request fluticasone furoate to be declared as a 'drug' for the purpose of section 85(2) of the National Health Act (Cth)(Act); and the listing instruments for each Breo Ellipta, Seretide and Flixotide be amended to reflected the full name of the active component of the respective inhaled corticosteroid of each product.

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

Closing date for consumer comments 8 February 2017

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.)
Change to listing (Minor Submission) WITHDRAWN	1. LUTROPIN ALFA 2. FOLLITROPIN WITH LUTROPIN ALFA 1. Powder for injection 75 I.U. with solvent 2. Powder for injection 150 I.U.-75 I.U. with solvent 1. Luveris® 2. Pergoveris® Merck Serono Pty Ltd	Stimulation of follicular development	To request the addition of a General Schedule Restricted Benefit listing for the stimulation of follicular development to the current Section 100 (In-Vitro Fertilisation) Authority Required (STREAMLINED) listing.
New listing (Major Submission)	MESALAZINE Tablet (enteric coated) 800 mg Asacol® Baxter Healthcare Pty Ltd	Ulcerative colitis	To request an Authority Required (STREAMLINED) listing for treatment of ulcerative colitis.
New listing (Major Submission)	METHOTREXATE Injection 7.5 mg in 0.15 mL pre-filled syringe Injection 10 mg in 0.2 mL pre-filled syringe Injection 15 mg in 0.3 mL pre-filled syringe Injection 20 mg in 0.4 mL pre-filled syringe Injection 25 mg in 0.5 mL pre-filled syringe Trexject® Link Medical Products Pty Ltd	Rheumatoid arthritis and psoriasis	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of rheumatoid arthritis and psoriasis for use in patients where the oral tablet form of methotrexate is unsuitable.

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

Closing date for consumer comments 8 February 2017

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)	MIGALASTAT Capsule 150 mg Galafold® Amicus Therapeutics	Fabry disease	To request a Section 100 (Highly Specialised Drug Program) Authority Required listing for the treatment of Fabry disease.
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	Renal cell carcinoma (RCC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for second-line treatment of clear cell variant renal cell carcinoma.

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

Closing date for consumer comments 8 February 2017

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)	NIVOLUMAB with IPILIMUMAB Nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL Opdivo® with Yervoy® Bristol-Myers Squibb Australia Pty Ltd	Metastatic melanoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with unresectable metastatic melanoma.
Change to listing (Major Submission) WITHDRAWN	OCTREOTIDE Injection (modified release) 10 mg (as acetate), vial and diluent syringe Injection (modified release) 20 mg (as acetate), vial and diluent syringe Injection (modified release) 30 mg (as acetate), vial and diluent syringe Sandostatin® LAR® Novartis Pharmaceuticals Australia Pty Ltd	Non-functional neuroendocrine tumours of midgut or suspected midgut origin	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for treatment of unresectable or metastatic, well-differentiated non-functional neuroendocrine tumours.

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

Closing date for consumer comments 8 February 2017

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)	PALBOCICLIB Capsule 75 mg Capsule 100 mg Capsule 125 mg Ibrance® Pfizer Australia Pty Ltd	Hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer	To request an Authority Required listing with a non-steroidal aromatase inhibitor (letrozole or anastrozole) as initial endocrine-based therapy in postmenopausal women with hormone receptor positive, HER2 negative advanced breast cancer.
Change to listing (Major Submission)	PEMBROLIZUMAB Injection concentrate for I.V. infusion 100 mg in 4 mL Powder for injection 50 mg Keytruda® Merck Sharp and Dohme (Australia)	Non-small cell lung cancer	To request a listing under Section 100 (Efficient Funding of Chemotherapy) as first line monotherapy in patients expressing PD-L1 for non-small cell lung cancer.
Change to listing (Minor Submission)	POMALIDOMIDE Capsule 3 mg Capsule 4 mg Pomalyst® Celgene Pty Ltd	Relapsed/refractory multiple myeloma (RRMM)	To request an amendment to the Section 100 (Highly Specialised Drugs) listing to include patients with relapsed or refractory multiple myeloma who have received treatment with both lenalidomide and bortezomib and have experienced severe intolerance or toxicity unresponsive to adjusted dose or scheduling of lenalidomide and/or bortezomib.

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

Closing date for consumer comments 8 February 2017

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.)
Change to listing (Minor Submission) WITHDRAWN	PROGESTERONE Vaginal gel (prolonged release) 90 mg in single dose pre-filled applicator Crinone® Merck Serono Australia Pty Ltd	Assisted reproductive technology	To request a change to the Section 100 (In-Vitro Fertilisation) listing to include the MBS item 13215 in the PBS restriction, to allow use in 'thaw' IVF cycles.
New listing (Major Submission)	RANOLAZINE Tablet (modified release) 375 mg Tablet (modified release) 500 mg Tablet (modified release) 750 mg Ranexa® Menarini Australia Pty Ltd	Stable angina pectoris	To request an Authority Required (STREAMLINED) listing as an add-on therapy for the symptomatic treatment of stable angina pectoris.
New listing (Minor Submission)	RITUXIMAB Solution for subcutaneous injection 1600 mg in 13.4 mL MabThera SC® Roche Products Pty Ltd	Chronic lymphocytic leukaemia (CLL)	To request a General Schedule and Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new presentation of rituximab for the treatment of CLL.

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

Closing date for consumer comments 8 February 2017

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)	SELEXIPAG Tablet 200 mcg Tablet 400 mcg Tablet 600 mcg Tablet 800 mcg Tablet 1000 mcg Tablet 1200 mcg Tablet 1400 mcg Tablet 1600 mcg Uptravi® Actelion Pharmaceuticals Australia Pty Ltd	Pulmonary arterial hypertension	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing as an add-on therapy for the treatment of pulmonary arterial hypertension.
New listing (Major Submission)	TENOFOVIR ALAFENAMIDE Tablet 25 mg Vemlidy® Gilead Sciences Pty Ltd	Chronic hepatitis B	To request an Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis B infection.

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

Closing date for consumer comments 8 February 2017

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)	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	To request an Authority Required listing for the treatment of autosomal dominant polycystic kidney disease.
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	A resubmission to request an Authority Required (STREAMLINED) listing for the treatment of metastatic colorectal cancer.

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

Closing date for consumer comments 8 February 2017

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.)
Change to listing (Minor Submission)	1. TRIGLYCERIDES LONG CHAIN 2. MEDIUM CHAIN TRIGLYCERIDES 1. Oral liquid 250 mL, 18 (Carbzero) 2. Oral liquid 250 mL, 18 (Betaquik) 1. CarbZero® 2. Betaquik® Vitaflo Australia Pty Ltd	1. Ketogenic diet 2. Ketogenic diet; dietary management of conditions requiring a source of medium chain triglycerides	To request a change in nutritional profile and packaging for CarbZero® and Betaquik®.
New listing (Major Submission)	ULIPRISTAL Tablet 5 mg Esmya® Vifor Pharma Pty Ltd	Moderate to severe symptoms of uterine fibroids	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age.
New listing (Minor Submission)	URSODEOXYCHOLIC ACID Tablet 500 mg Ursofalk® Orphan Australia Pty Ltd	Primary biliary cirrhosis	To request an Authority Required (STREAMLINED) listing of a new strength for the treatment of primary biliary cirrhosis

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

Closing date for consumer comments 8 February 2017

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.)
Change to listing (Major Submission)	USTEKINUMAB Injection concentrate for I.V. infusion 130 mg in 26 mL Injection 45 mg in 0.5 mL Stelara® Janssen-Cilag Pty Ltd	Crohn disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the single intravenous induction dose and a Section 85 Authority Required listing for all subcutaneous doses thereafter for the treatment of severe Crohn disease and complex refractory fistulating Crohn disease.
New listing (Major Submission)	VENETOCLAX Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd	Relapsed/refractory chronic lymphoid leukaemia (CLL)	To request an Authority Required listing for the treatment of relapsed/refractory CLL.
Sub-committee report (DUSC analysis)	Imatinib Glivec® Alphapharm Pty Ltd	Gastrointestinal stromal tumour (GIST)	To compare the predicted versus actual use of imatinib for GIST 24 months after the listing was extended to allow an increase in its total treatment duration from 12 months to 36 months.
Sub-committee report (DUSC analysis)	Everolimus Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Metastatic breast cancer	To compare the predicted versus actual use of everolimus for metastatic breast cancer.

Closing date for consumer comments 8 February 2017

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.)
Sub-committee report (DUSC analysis)	Everolimus Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Tuberous sclerosis complex	To compare the predicted versus actual use of everolimus for tuberous sclerosis complex (TSC).
Sub-committee report (DUSC analysis)	Ferric carboxymaltose Ferinject® Vifor Pharma Pty Ltd	Iron deficiency anaemia	To compare the predicted versus actual use of ferric carboxymaltose 24 months after its PBS listing
Sub-committee report (DUSC analysis)	Erlotinib, Tarceva®, Roche Products Pty Ltd Gefitinib, Iressa®, AstraZeneca Pty Ltd	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer	To compare the predicted versus actual use of the tyrosine kinase inhibitors, erlotinib and gefitinib.
Sub-committee report (DUSC analysis)	Metformin Metformin+glibenclamide Glibenclamide Gliclazide Glimepiride Glipizide Pioglitazone Rosiglitazone Rosiglitazone+metformin Alogliptin Alogliptin+metformin Linagliptin Linagliptin+metformin Saxagliptin Saxagliptin+metformin Sitagliptin Sitagliptin+metformin	Diabetes	To review the utilisation of medicines used to treat diabetes.

Closing date for consumer comments 8 February 2017

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.)
	Vildagliptin Vildagliptin+metformin Exenatide Dapagliflozin Dapagliflozine+metformin Empagliflozin+metformin EmpagliflozinAcarbose Insulin and analogues (all current and previously listed brands including generic versions)		