

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
MARCH 2018 PBAC MEETING**

**Closing date for consumer comments 7 February 2018\***

\*NOTE: that the closing date for consumer comments is 24 January 2018 for the following submissions:

- **MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE (Nimenrix®/Pfizer Australia Pty Ltd) for the active immunisation of infants for meningococcal disease.**
- **TRIVALENT INFLUENZA VACCINE (Fluzone® High-Dose/Sanofi-aventis Australia Pty Ltd) for the prevention of seasonal influenza in patients aged 65 years and over.**
- **TRIVALENT INFLUENZA VACCINE (Fluad®/Seqiris Australia Pty Ltd) for the prevention of seasonal influenza in patients aged 65 years and over.**

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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<b>Submission type</b> (new listing, change to listing)	<b>Drug Name, form(s), strength(s) and Sponsor</b> (Drug name, form, strength, Trade name®, Sponsor)	<b>Drug Type and Use</b> (What is the drug used to treat?)	<b>Listing requested by Sponsor / Purpose of Submission</b> (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)	ABATACEPT  Injection 125 mg in 1 mL single dose autoinjector Injection 125 mg in 1 mL single dose pre-filled syringe Powder for I.V. infusion 250 mg  Orencia® Orencia ClickJect®  Bristol-Myers Squibb Australia Pty Ltd	Psoriatic arthritis (PsA)	To request an Authority Required listing for the treatment of patients with severe active PsA.
Change to recommended listing  (Minor Submission)	ADRENALINE  I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector  AdrenaJect®  Sun Pharma ANZ Pty Ltd	Anaphylaxis	To request that the PBAC reconsider its previous recommendation that AdrenaJect not be considered equivalent for the purposes of substitution with the reference originator.

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Change to listing  (Minor Submission)	1) AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE 2) AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE 3) AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE  Oral liquid 87 mL, 30; Oral liquid 130 mL, 30; and Oral liquid 174 mL, 30  1) MSUD cooler 10, 15 and 20; 2) TYR cooler 10, 15 and 20; and 3) HCU cooler 10, 15 and 20  Vitaflo Australia Pty Ltd	1)Maple Syrup Urine Disease (MSUD) 2)Tyrosinaemia (TYR) 3)Homocystinuria (HCU)	To request changes to the Restricted Benefit listings of MSUD, TYR and HCU Coolers including nutritional content.
New listing  (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS, WITHOUT PHENYLALANINE  Oral powder 400 g (PKU Start)  PKU Start®  Vitaflo Australia Pty Ltd	Phenylketonuria	To request a Restricted Benefit listing for the dietary management of patients with phenylketonuria.

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New listing  (Minor Submission)	APOMORPHINE  Solution for subcutaneous infusion containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen  Movapo Pen  Stada Pharmaceuticals Australia Pty Ltd	Parkinson disease	To request a Section 100 (Highly Specialised Drugs Program - Public and Private Hospital) listing of a new form of apomorphine.
New listing  (Minor Submission)	APREMILAST  Tablet 30 mg Pack containing 4 tablets of 10 mg , 4 tablets of 20 mg and 19 tablets of 30 mg  Otezla®  Celgene Pty Ltd	Moderate to severe plaque psoriasis	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe plaque psoriasis.
New listing  (Minor Submission)	ARGININE  Tablet 500 mg  Arginine Easy®  Orpharma Pty Ltd	Urea cycle disorders (UCD)	To request a Restricted Benefit listing for the treatment of UCD.

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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)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) listing for the treatment of patients with juvenile onset HPP who meet certain conditions.
New listing  (Major Submission)	BENRALIZUMAB  30mg in 1 mL solution for injection prefilled syringe  Fasentra®  AstraZeneca Pty Ltd	Uncontrolled severe eosinophilic asthma	To request a Section 100 (Highly Specialised Drug Program) Authority Required listing for the treatment of uncontrolled severe eosinophilic asthma in patients aged 18 years and over.
Change to listing  (Minor Submission)	BENRALIZUMAB  30mg in 1 mL solution for injection prefilled syringe  Fasentra®  AstraZeneca Pty Ltd	Uncontrolled severe eosinophilic asthma	To request amendments to the current Section 100 (Highly Specialised Drugs Program - Public and Private Hospital) restrictions for uncontrolled severe eosinophilic asthma.
Change to recommended listing  (Major Submission)	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX  Lyophilised powder for injection 100 units  Botox®  Allergan Australia Pty Limited	Chronic migraine	To request a revision to the existing risk sharing arrangements.

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Change to listing  (Minor Submission)	CALCIPOTRIOL with BETAMETHASONE  Gel containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g  Daivobet 50/500® Gel  Leo Pharma Pty Ltd	Chronic stable plaque type psoriasis vulgaris	To request additional Authority Required (STREAMLINED) listings with increased maximum quantities based on percentage of Body Surface Area (BSA) to be treated.
Change to listing  (Major Submission)	CETUXIMAB  Solution for I.V. infusion 100 mg in 20 mL Solution for I.V. infusion 500 mg in 100 mL  Erbix®  Merck Serono Australia Pty Ltd	Recurrent or metastatic squamous cell carcinoma of the head and neck	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck.
New listing  (Minor Submission)	CLADRIBINE  Tablet 10 mg  Mavenclad®  Merck Serono Australia Pty Ltd	Relapsing-remitting multiple sclerosis (RRMS)	Resubmission to request an Authority Required listing for the treatment of RRMS.
Change to listing  (Major Submission)	DEXAMETHASONE  Intravitreal injection 700 micrograms  Ozurdex®  Allergan Australia Pty Ltd	Macular oedema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).	To request an Authority Required listing for the treatment of macular oedema secondary to BRVO and CRVO.

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Change to recommended listing  (Minor Submission)	ECULIZUMAB  Solution concentrate for I.V. infusion 300 mg in 30 mL  Soliris®  Alexion Pharmaceuticals Australasia Pty Limited	Atypical haemolytic uraemic syndrome (aHUS) in end stage renal disease (ESRD)	To request an extension in the recommended eculizumab treatment duration for patients with aHUS in ESRD who are eligible for a renal transplant.
New listing  (Major Submission)	1) ERTUGLIFLOZIN 2) ERTUGLIFLOZIN WITH METFORMIN  1) Tablet containing 5 mg ertugliflozin; Tablet containing 15 mg ertugliflozin 2) Tablet containing 2.5 mg ertugliflozin with 500 mg metformin hydrochloride; Tablet containing 2.5 mg ertugliflozin with 1 g metformin hydrochloride; Tablet containing 7.5 mg ertugliflozin with 500 mg metformin hydrochloride; Tablet containing 7.5 mg ertugliflozin with 1 g metformin hydrochloride;  1) Steglatro® (TBC) 2) Segluromet® (TBC)  Merck Sharp & Dohme (Australia) Pty Limited	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for dual oral combination therapy for patients with T2DM who are inadequately controlled with metformin or a sulfonylurea.

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New listing  (Minor Submission)	ETANERCEPT  Injection 50 mg in 1 mL single use auto-injector, 4 Injection 50 mg in 1 mL single use pre-filled syringes, 4  Erelzi®  Sandoz Pty Ltd	Rheumatoid arthritis (RA), psoriatic arthritis (PsA), plaque psoriasis, ankylosing spondylitis, juvenile idiopathic arthritis (JIA), paediatric plaque psoriasis	To request an Authority Required listing for the same indications as the reference biologic.
Change to listing  (Minor Submission)	EVOLOCUMAB  Injection 420 mg in 3.5 mL single use pre-filled cartridge Injection 140 mg in 1 mL single use pre-filled pen  Repatha®  Amgen Australia Pty Limited	Familial hypercholesterolaemia (FH)	Resubmission to request an Authority Required listing for treatment of patients with FH who have either very high LDL-c or symptomatic atherosclerotic cardiovascular disease (ASCVD).
Change to listing  (Minor Submission)	FILGRASTIM  Injection 120 micrograms in 0.2 mL single use pre-filled syringe (Nivestim) Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Nivestim) Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Nivestim)  Nivestim®  Pfizer Australia Pty Ltd	Chemotherapy-induced neutropenia; Mobilisation of peripheral blood progenitor cells; Assisting bone marrow transplantation; Assisting autologous peripheral blood progenitor cell transplantation; Severe congenital neutropenia; Severe chronic neutropenia; Chronic cyclical neutropenia	To request that the current listings of Nivestim be changed to Authority Required (STREAMLINED) for Section 100 Highly Specialised Drugs (Private Hospital).

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Change to listing  (Minor Submission)	FOLLITROPIN ALFA  Injection 75 I.U. in 0.125 mL pre-filled pen Injection 150 I.U. in 0.25 mL pre-filled pen Injection 225 I.U. in 0.375 mL pre-filled pen Injection 300 I.U. in 0.5 mL pre-filled pen Injection 450 I.U. in 0.75 mL pre-filled pen  Bemfola®  Gedeon Richter Australia Pty Ltd	Assisted Reproductive Technology (ART); Anovulatory infertility; Infertility due to hypogonadotropic hypogonadism	To request that the current listings of Bemfola be changed to a Restricted Benefit (for the Section 100 IVF listings), and to include a NOTE encouraging prescribing for treatment-naïve patients.
Change to listing  (Minor Submission)	GRAZOPREVIR + ELBASVIR  Tablet containing grazoprevir 100 mg with elbasvir 50 mg  Zepatier™  Merck, Sharp and Dohme Australia Pty Limited	Chronic Hepatitis C virus infection	To request that the current General Schedule and Section 100 (Highly Specialised Drug) listings be changed to Authority Required (STREAMLINED) and amendments to the General Statement for Drugs for the treatment of Hepatitis C to allow for this change.
New listing  (Major Submission)	GUSELKUMAB  Injection 100 mg in 1 mL single use pre-filled syringe  Tremfya®  Janssen-Cilag Pty Ltd	Severe chronic plaque psoriasis	To request an Authority Required listing for the treatment of severe chronic plaque psoriasis.

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New listing  (Minor Submission)	HYDROMORPHONE  Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL  Dilaudid®  Mundipharma Pty Ltd	Severe disabling pain	To request a Restricted Benefit listing for the treatment of severe disabling pain.
Change to listing  (Minor Submission)	IBRUTINIB  Capsule 140 mg  Imbruvica®  Janssen-Cilag Pty Ltd	Chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL) and relapsed or refractory mantle cell lymphoma (MCL)	Resubmission to request an Authority Required listing for the first line treatment of patients with CLL or SLL who meet certain criteria and relapsed or refractory MCL.
New listing  (Minor Submission)	INSULIN DEGLUDEC WITH INSULIN ASPART  Injections, cartridges, 70 units-30 units per mL, 3 mL, 5 Injections, pre-filled pen, 70 units-30 units per mL, 3 mL, 5  Ryzodeg FlexTouch® Ryzodeg Penfill®  Novo Nordisk Pharmaceuticals Pty Ltd	Diabetes mellitus	Resubmission to request an unrestricted listing to improve glycaemic control in adult patients with diabetes mellitus where basal and prandial insulin treatment is necessary.

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New listing  (Major Submission)	INSULIN GLARGINE WITH LIXISENATIDE  Injections (human analogue), cartridges, insulin glargine 100 units per mL with lixisenatide 50 microgram per mL, 3 mL, 5 Injections (human analogue), cartridges, insulin glargine 100 units per mL with lixisenatide 33 microgram per mL, 3 mL, 5  Soliqua®  Sanofi-aventis Australia Pty Ltd	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for the treatment of patients with T2DM who have inadequate glycaemic control with basal insulin.
New listing  (Major Submission)	IRINOTECAN (NANOLIPOSOMAL)  Injection concentrate for I.V. infusion 43 mg (as sucrosfate) in 10 mL  Onivyde®  Shire Australia Pty Ltd	Metastatic pancreatic cancer	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of metastatic pancreatic cancer in combination with 5-fluorouracil and folinic acid (5-FU/LV) in patients who have progressed following treatment with a gemcitabine based regimen.
Change to listing  (Major Submission)	LENALIDOMIDE  Capsule 5 mg Capsule 10 mg Capsule 15 mg  Revlimid®  Celgene Pty Ltd	Multiple myeloma	To request extension to the Section 100 (Highly Specialised Drug Program) Authority Required listing to include maintenance treatment of patients with newly diagnosed multiple myeloma who have undergone an autologous stem cell transplant.

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Change to recommended listing  (Minor Submission)	LENVATINIB  Capsule 10 mg (as mesilate) Capsule 4 mg (as mesilate)  Lenvima®  Eisai Australia Pty Ltd	Advanced renal cell carcinoma	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with advanced renal cell carcinoma following treatment with at least one anti-angiogenic therapy.
Change to recommended listing  (Minor Submission)	LIRAGLUTIDE  Injection 6 mg/mL, 3mL pre-filled pen  Victoza®  Novo Nordisk Pharmaceuticals Pty Limited	Type 2 diabetes mellitus (T2DM)	To request an amendment to the recommended listing to include a Special Pricing Arrangement.
New listing  (Major Submission)	MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE  Injection 0.5 mL in pre-filled syringe  Nimenrix®  Pfizer Australia Pty Ltd	Meningococcal disease	To request listing on the National Immunisation Program (NIP) for the active immunisation of infants.
New listing  (Major Submission)	MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE  Injection 0.5 mL in pre-filled syringe  Nimenrix®  Pfizer Australia Pty Ltd	Meningococcal disease	To request listing on the National Immunisation Program (NIP) for the immunisation of adolescents in Year 10 and a catch-up program for adolescents aged up to 19 years administered via a school or GP-based catch up program.

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Change to listing  (Minor Submission)	MEPOLIZUMAB  Powder for injection 100 mg  Nucala®  GlaxoSmithKline Australia Pty Ltd	Severe eosinophilic asthma	To request changes to the current Section 100 (Highly Specialised Drugs Program) Authority Required listing by removing the 6 month waiting period between the reuse of, or switching between omalizumab and mepolizumab.
New listing  (Minor Submission)	NANDROLONE DECANOATE  Injection 50 mg in 1 mL ampoule  Deca-Durabolin®  Aspen Pharmacare Australia Pty Ltd	Osteoporosis	To request an Authority Required listing of a new form of nandrolone decanoate for the treatment of osteoporosis.
New listing  (Other 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.

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Change to 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	Squamous cell carcinoma for the head and neck (SCCHN)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with squamous cell carcinoma of the head and neck (SCCHN) who progress within 6 months following platinum-based therapy.
New listing  (Minor Submission)	NUSINERSEN  Solution for injection 12 mg in 5 mL  Spinraza™  Biogen Australia Pty Ltd	Treatment of infantile-onset (Type I) spinal muscular atrophy (SMA)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of Type I SMA.
Change to listing  (Minor Submission)	OBINUTUZUMAB  Solution for I.V. infusion 1000 mg in 40 mL  Gazyva®  Roche Products Pty Ltd	CD20 positive follicular lymphoma	Resubmission to request an Authority Required (STREAMLINED) listing for untreated patients with Stage II bulky or Stage III/IV CD20 positive follicular lymphoma or rituximab-refractory follicular lymphoma.
New listing  (Major Submission)	OLAPARIB  Tablet 100 mg Tablet 150 mg  Lynparza®  AstraZeneca Pty Ltd	High-grade serous ovarian, fallopian tube and primary peritoneal cancer	To request an Authority Required listing for the treatment of high-grade serious ovarian, fallopian tube and primary peritoneal cancer.

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Change to listing  (Minor Submission)	OMALIZUMAB  Injection 150 mg in 1 mL single dose pre-filled syringe  Xolair®  Novartis Pharmaceuticals Australia Pty Ltd	Severe chronic spontaneous urticaria	To request a General Schedule Authority Required listing for the treatment of severe chronic spontaneous urticaria in addition to the current Section 100 (Highly Specialised Drug) listing.
New listing  (Minor Submission)	PALBOCICLIB  Capsule 75 mg Capsule 100 mg Capsule 125 mg  Ibrance®  Pfizer Australia Pty Ltd	Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer	Resubmission to request an Authority Required listing as initial endocrine-based therapy in patients with HR+, HER2- locally advanced, inoperable or metastatic breast cancer in combination with a non-steroidal aromatase inhibitor.
Change to listing  (Minor Submission)	PEMBROLIZUMAB  Powder for injection 50 mg Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck, Sharp & Dohme (Australia) Pty Ltd	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as first line monotherapy in patients expressing PD-L1 for NSCLC.

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Change to listing  (Minor Submission)	PEMBROLIZUMAB  Powder for injection 50 mg Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck, Sharp and Dohme (Australia) Pty Limited	Melanoma	To request a change to the dosing regimen to a fixed dose, from weight-based dosing, with a new maximum amount.
New listing  (Minor Submission)	PERFLUOROHEXYLOCTANE  Eye drops containing perfluorohexyloctane, 3 mL  NovaTears®  AFT Pharmaceuticals Pty Ltd	Severe dry eye syndrome	To request an Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome.
New listing  (Minor Submission)	PIRFENIDONE  Tablet 267 mg Tablet 801 mg  Esbriet®  Roche Products Pty Ltd	Idiopathic pulmonary fibrosis	To request an Authority Required listing for two new forms of pirfenidone.
Change to listing  (Minor Submission)	PNEUMOCOCCAL CONJUGATE VACCINE, 13 VALENT  Injection 0.5 mL  Prevenar 13®  Pfizer Australia Pty Ltd	Prevention of pneumococcal disease	To request a change to the National Immunisation Program (NIP) infant schedule for 13-valent pneumococcal vaccine from a 3+0 to a 2+1 schedule.

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Change to listing (Minor Submission)	PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES  Oral powder 450 g (Aptamil Gold+ Pepti-Junior)  Aptamil Gold+ Pepti-Junior®  Danone Nutricia	Cow's milk protein enteropathy and intolerance to soy protein; Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein; Biliary atresia; Chronic liver failure with fat malabsorption; Chylous ascites; Cystic fibrosis; Enterokinase deficiency; Proven fat malabsorption; Severe diarrhoea of greater than 2 weeks duration; Severe intestinal malabsorption including short bowel syndrome	To request changes to the Authority Required (STREAMLINED) listing of Aptamil Gold+ Pepti-Junior including nutritional content.
New listing (Major Submission)	RAMUCIRUMAB  Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 500 mg in 50 mL  Cyramza®  Eli Lilly Australia Pty Ltd	Advanced gastric or gastro-oesophageal junction adenocarcinomas	To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with advanced or metastatic, gastric or gastro-oesophageal junction adenocarcinoma in with disease progression, in combination with paclitaxel after prior platinum and fluoropyrimidine chemotherapy.

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Change to listing  (Major Submission)	RANIBIZUMAB  Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe Solution for intravitreal injection 2.3 mg in 0.23 mL  Lucentis®  Novartis Pharmaceuticals Australia Pty Ltd	Visual impairment due choroidal neovascularisation (CNV)	To request an Authority Required listing for the treatment of patients with rare choroidal neovascularisation CNV secondary to pathologic myopia.
Change to listing  (Major Submission)	RANIBIZUMAB  Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe Solution for intravitreal injection 2.3 mg in 0.23 mL  Lucentis®  Novartis Pharmaceuticals Australia Pty Ltd	Visual impairment due to choroidal neovascularisation (CNV)	To request an Authority Required listing for the treatment of patients with visual impairment due to rare CNV.
New Listing  (Minor Submission)	RANOLAZINE  Tablet (modified release) 375 mg Tablet (modified release) 500 mg Tablet (modified release) 750 mg  Ranexa®  A. Menarini Australia Pty Ltd	Stable angina pectoris	Resubmission to request an Authority Required listing as an add-on therapy for the symptomatic treatment of stable angina pectoris.

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New listing  (Major Submission)	REGORAFENIB  Tablet 40 mg (as monohydrate)  Stivarga®  Bayer Australia Ltd	Hepatocellular carcinoma (HCC)	To request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable HCC who have progressed on sorafenib treatment.
New listing  (Minor 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	Resubmission to request an Authority Required listing as initial endocrine-based therapy in patients with HR+, HER2- locally advanced, inoperable or metastatic breast cancer in combination with a non-steroidal aromatase inhibitor, who are not premenopausal.
New listing  (Minor Submission)	RITUXIMAB  Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL  Riximyo®  Sandoz Pty Ltd	CD20 positive follicular B-cell non-Hodgkin's lymphoma; Severe active granulomatosis with polyangiitis (Wegeners granulomatosis); CD20 positive non-Hodgkin's lymphoma; Low-grade B-cell non-Hodgkin's lymphoma; Chronic lymphocytic leukaemia; Severe active rheumatoid arthritis	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) and Section 100 Authority Required (Highly Specialised Drug) listings for the same indications as the reference biologic.
Change to listing  (Major Submission)	SAPROPTERIN  Tablet (soluble) containing sapropterin dihydrochloride 100 mg  Kuvan®  BioMarin Pharmaceutical Australia Pty Ltd	Hyperphenylalaninemia (HPA)	To request an Authority Required listing for the treatment of HPA in patients with phenylketonuria.

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New listing  (Minor Submission)	SODIUM PHENYLBUTYRATE  Granules 483 mg (as sodium) per g, 174 g  Pheburane®  Orpharma Pty Ltd	Urea cycle disorder (UCD)	Resubmission to request an Authority Required listing for the treatment of patients with UCD.
New listing  (Major Submission)	SOFOSBUVIR WITH VELPATASVIR WITH VOXILAPREVIR  Tablet containing sofosbuvir 400 mg with velpatasvir 100 mg and voxilaprevir 100 mg  Vosevi®  Gilead Sciences Pty Ltd	Chronic hepatitis C virus (HCV) infection	To request a General Schedule and Section 100 (Highly Specialised Drugs Program) listing for the treatment of HCV infection in adults who have failed treatment with an NS5A-based direct acting antiviral treatment regimen, regardless of genotype.
New listing  (Major Submission)  WITHDRAWN	STIRIPENTOL  Capsule 250 mg Capsule 500 mg Powder for oral suspension 250 mg Powder for oral suspension 500 mg  Diacomit®  Emerge Health Pty Ltd	Severe myoclonic epilepsy in infancy (SMEI)	To request an Authority Required (STREAMLINED) listing for treatment in combination with sodium valproate and clobazam as adjunctive treatment of generalised tonic-clonic and clonic seizures in patients with SMEI (Dravet Syndrome) whose seizures are not adequately controlled with sodium valproate and clobazam.

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New listing  (Major Submission)	TENOFOVIR ALAFENAMIDE WITH EMTRICITABINE AND BICTEGRAVIR  Tablet containing tenofovir alafenamide 25 mg with emtricitabine 200 mg and bicittegravir 50 mg  Trade name to be determined  Gilead Sciences 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.
Change to listing  (Major 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 an Authority Required (STREAMLINED) listing for the treatment of severe asthma in children aged 6 years or older.
New listing  (Major Submission)	TOLVAPTAN  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)	Resubmission to request an Authority Required listing for the treatment of ADPKD.

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New listing  (Major Submission)	TRAMADOL HYDROCHLORIDE WITH PARACETAMOL  Tablet containing tramadol hydrochloride 37.5 mg with paracetamol 325 mg  Zaldiar®  Aspen Pharmacare Australia Pty Ltd	Acute and chronic pain	To request a Restricted Benefit listing for the treatment of acute and chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed.
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, LONG CHAIN WITH GLUCOSE POLYMER  Oral liquid 250 mL, 18 (ProZero) Oral liquid 1 L, 6 (ProZero)  ProZero  Vitaflo Australia Pty Ltd	Proven inborn errors of protein metabolism	To request changes to the Restricted Benefit listing of ProZero including nutritional content.

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New listing (Minor Submission)	TRIVALENT INFLUENZA VACCINE (High dose)  Injection 0.5 mL  Fluzone® High-Dose  Sanofi-aventis Australia Pty Ltd	Prevention of seasonal influenza	To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.
New listing (Minor Submission)	TRIVALENT INFLUENZA VACCINE  Injection 0.5 mL  Fluad®  Seqirus (Australia) Pty Ltd	Prevention of seasonal influenza	To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.
Matters relating to PBS Review  (DUSC Analysis)	Fluconazole (Diflucan®, Pfizer Australia Pty Ltd); (Dizole®, Fluconazole Alphapharm®, Alphapharm Pty Ltd); (Fluconazole-Sandoz®, Sandoz Pty Ltd); (Ozole®, Sun Pharma ANZ Pty Ltd); (APO-fluconazole®, Apotex Pty Ltd); (Fluzole®, Arrow Pharma Pty Ltd)  Itraconazole (Lozanoc®, Mayne Pharma International Pty Ltd); (Sporanox®, Janssen-Cilag Pty Ltd); (APO-itraconazole®, Apotex Pty Ltd); (Itranox®, Arrow Pharma Pty Ltd); (Itracap®, Alphapharm Pty Ltd);	Antifungals	To consider options to address the increasing use of PBS subsidised fluconazole and itraconazole after they changed from Authority Required (STREAMLINED) to Restricted Benefit listings.

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Matters relating to PBS Review  (DUSC Analysis)	Prescriber bag medicines	Drugs used for emergencies	To review currently listed drugs and consider requests to add new drugs and prescriber types.
Sub-committee report  (DUSC Analysis)	Bevacizumab (Avastin®, Roche Products Pty Ltd); Cetuximab (Erbix®, Merck Serono Australia Pty Ltd); Panitumumab (Vectibix®, Amgen Australia Pty Limited)	Metastatic colorectal cancer	To assess the utilisation of targeted therapies for metastatic colorectal cancer; including PBS listed bevacizumab, cetuximab and panitumumab.
Sub-committee report  (DUSC Analysis)	Trastuzumab (Herceptin®, Herceptin® SC, Roche Products Pty Ltd); Trastuzumab emtansine (Kadcyla®, Roche Products Pty Ltd); Pertuzumab (Perjeta®, Roche Products Pty Ltd)	HER2 positive metastatic breast cancer	To compare the predicted and actual utilisation of trastuzumab, trastuzumab emtansine and pertuzumab for HER2 positive metastatic breast cancer.
Sub-committee report  (DUSC Analysis)	Ivacaftor (Kalydeco®, Vertex Pharmaceuticals (Australia) Pty Ltd)	Cystic fibrosis	To report on the predicted versus actual use of ivacaftor in the treatment of cystic fibrosis.

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Matters relating to PBS Review  (Evaluation of Post market review)	Omeprazole Pantoprazole Lansoprazole Rabeprazole Esomeprazole Esomeprazole, clarithromycin & amoxicillin Omeprazole, amoxicillin & clarithromycin (delisted in 2014)  (all current and previously listed brands including generic versions)	Gastro-oesophageal reflux disorders	To consider a drug utilisation review of use of PBS listed Proton Pump Inhibitor medicines and review DUSC's consideration of the findings.

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Matters relating to PBS Review  (Evaluation of Post market review)	Salbutamol Terbutaline Ipratropium Beclomethasone Fluticasone Budesonide Ciclesonide Sodium cromoglycate Nedocromil sodium Montelukast Salmeterol Eformoterol Fluticasone with Salmeterol Fluticasone with Eformoterol Fluticasone with Vilanterol Budesonide with Eformoterol Oral glucocorticoids, plain  (all listed brands)	Asthma	To consider the findings from the evaluation of the 2014 Post market review of PBS medicines used to treat asthma in children.