

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2015 PBAC MEETING**

Closing date for consumer comments 11 February 2015

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 re-submissions (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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| Submission type <i>(new listing, change to listing)</i> | Drug Name, form(s), strength(s) and Sponsor <i>(Drug name, form, strength, Trade name[®], Sponsor)</i> | Drug Type and Use <i>(What is the drug used to treat?)</i> | Listing requested by Sponsor / Purpose of Submission <i>(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased)</i> |
|---|--|---|--|
| Change to listing (Minor Submission) | AFLIBERCEPT 4 mg/0.1 mL injection, 1 x 0.1 mL vial, 4 mg/0.1 mL injection, 1 x 0.09 mL syringe Eylea [®] Bayer Australia Ltd | Age related macular degeneration (AMD), central retinal vein occlusion (CRVO) and diabetic macular oedema (DME) | To request that the vial and syringe presentations be designated as equivalent for substitution purposes (i.e. 'a'-flagged). |
| New listing (Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN oral liquid: powder for, 500 g XYLYS LOW TRY Maxamum [®] Nutricia Australia Pty Ltd | Medicinal food | Restricted benefit listing for patients over 8 years of age with glutaric aciduria. |
| New listing (Minor Submission) | AMINO ACID SYNTHETIC FORMULA oral liquid: powder for, 400 g Alfamino [®] Junior Nestle Australia Ltd | Medicinal food | To list a new formulation suitable for children aged 1 year and older for the same indications as the existing Alfamino product listed on the PBS, as well as for severe intestinal malabsorption including short bowel syndrome. |

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| Change to listing (Minor Submission) | ANTI-GLAUCOMA DRUGS various Optometry Australia on behalf of various sponsors | Glaucoma | To amend existing arrangements so that patients treated by an optometrist can access anti-glaucoma medications through the PBS without the requirement for the prescribing optometrist to be working in shared care arrangements with an ophthalmologist. |
| Change to listing (Major Submission) | APIXABAN 2.5 mg tablet, 60 5 mg tablet, 28 5 mg tablet, 60 Eliquis [®] Bristol-Myers Squibb Australia Pty Ltd | Deep vein thrombosis or pulmonary embolism | To request Authority Required (STREAMLINED) listing for the treatment of deep vein thrombosis or pulmonary embolism. |
| New listing (Major Submission) | APREMILAST 30 mg tablet, 56 Starter Pack (10 mg tablet, 4; 20 mg tablet, 4; and 30 mg tablet, 19) Otezla [®] Celgene Pty Ltd | Moderate to severe plaque psoriasis | To request Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe plaque psoriasis. |

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| New listing (Major Submission) | APREMILAST 30 mg tablet, 56 Starter Pack (10 mg tablet, 4; 20 mg tablet, 4; and 30 mg tablet, 19) Otezla [®] Celgene Pty Ltd | Severe active psoriatic arthritis | To request Authority Required (STREAMLINED) listing for the treatment of severe active psoriatic arthritis. |
| New listing (Major Submission) | ASUNAPREVIR 100 mg capsule, 56 Sunvepra [®] Bristol-Myers Squibb Australia Pty Ltd | Hepatitis C | To request Authority Required (STREAMLINED) listing for the treatment of chronic genotype 1b hepatitis C virus infection. |
| New listing (Major Submission) | BENDAMUSTINE HYDROCHLORIDE 25 mg injection: powder for, 1 vial 100 mg injection: powder for, 1 vial Ribomustin [®] Janssen-Cilag Pty Ltd | Stage III and stage IV indolent non-Hodgkin's lymphoma and mantle cell lymphoma | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of stage III and stage IV indolent non-Hodgkin's lymphoma and mantle cell lymphoma. |

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| Change to listing (Major Submission) | BRENTUXIMAB VEDOTIN 50 mg injection: powder for, 1 vial Adcetris [®] Takeda Pharmaceuticals Australia Pty Ltd | Hodgkin lymphoma | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of Hodgkin lymphoma relapsed or refractory after autologous stem cell transplant. |
| New listing (Minor Submission) | BUPRENORPHINE 15 microgram/hour patch, 2 25 microgram/hour patch, 2 30 microgram/hour patch, 2 40 microgram/hour patch, 2 Norspan [®] Mundipharma Pty Ltd | Pain | To list additional strengths for the same indications currently applying to the existing patches. |
| New listing (Major Submission) | CANAKINUMAB 150 mg injection: powder for, 1 vial 150 mg injection: powder for, 4 vials Ilaris [®] Novartis Pharmaceuticals Australia Pty Ltd | Systemic juvenile idiopathic arthritis | To request Authority Required listing for the treatment of systemic juvenile idiopathic arthritis. |

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|---|--|--|---|
| New listing (Major Submission) | DACLATASVIR 30 mg tablet, 28 60 mg tablet, 28 Daklinza [®] Bristol-Myers Squibb Australia Pty Ltd | Hepatitis C | To request Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis C virus infection. |
| Change to listing (Major Submission) | DAPAGLIFLOZIN 10 mg tablet, 28 Forxiga [®] AstraZeneca Australia Pty Ltd | Type 2 diabetes mellitus | To request Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus. |
| New listing (Major Submission) | DEXAMETHASONE 700 microgram implant, 1 Ozurdex [®] Allergan Australia Pty Ltd | Treatment of diabetic macular oedema | To request Authority Required (STREAMLINED) listing for the treatment of visual impairment due to diabetic macular oedema in patients with pseudophakia (ie, artificial lens following cataract surgery) or who are scheduled for cataract surgery. |

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| New listing (Major Submission) | Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (DTPa-HepB-IPV-Hib) 0.5 mL pre-filled syringe Hexaxim [®] Sanofi-Aventis Australia Pty Ltd | Diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b | To request the inclusion of DTPa-HepB-IPV-Hib on the National Immunisation Program for the primary vaccination of infants at 2, 4 and 6 months of age. |
| Change to listing (Major Submission) | ETANERCEPT 50 mg injection in 1mL single use auto-injector, 4 pack 50 mg injection in 1 mL single use pre-filled syringes, 4 pack 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack Enbrel [®] Pfizer Australia Pty Ltd | Nonradiographic axial spondyloarthritis | To request Authority Required listing for the treatment of nonradiographic axial spondyloarthritis. |

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| New listing (Major Submission) | EVOLOCUMAB 140 mg/1 mL injection, 1 x 1 mL injection device (Trade name to be confirmed) Amgen Australia Pty Ltd | Hypercholesterolaemia | To request Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia. |
| Change to listing (Major Submission) | EXENATIDE 5 microgram/0.02 mL injection: solution, 60 unit doses 10 microgram/0.04 mL injection: solution, 60 unit doses Byetta [®] AstraZeneca Australia Pty Ltd | Type 2 diabetes mellitus | To request Authority Required (STREAMLINED) listing for use in combination with insulin in type 2 diabetes mellitus. |
| New listing (Major Submission) | FEBUXOSTAT 80 mg tablet, 28 120 mg tablet, 28 Adenuric [®] A.Menarini Australia Pty Ltd | Hyperuricaemia with deposition | To request Authority Required (STREAMLINED) listing for the treatment of chronic symptomatic hyperuricaemia with deposition (chronic gout). |

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| New listing (Minor Submission) | FOLLITROPIN ALFA (RCH) + LUTROPIN ALFA (RCH) follitropin alfa (rch) 150 IU + lutropin alfa (rch) 75 IU injection Pergoveris [®] Merck Serono Australia Pty Ltd | Assisted reproduction | To request Section 100 (IVF/GIFT Program) Authority Required listing for patients who are receiving treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule who have severe luteinising hormone deficiency and for whom treatment with the combination product is considered to be appropriate. |
| New listing (Minor Submission) | GLATIRAMER 40 mg/mL injection, 12 x 1 mL syringes Copaxone 40 [®] bioCSL Pty Ltd | Multiple sclerosis | To request Authority Required listing of a new strength for the same indications as the existing 20 mg/mL pre-filled syringe. |
| New listing (Minor Submission) | GLUCOSE INDICATOR BLOOD glucose indicator blood strip: diagnostic, 100 Betachek C50 [®] National Diagnostic Products Pty Ltd | Blood glucose monitoring | Unrestricted benefit listing (5 repeats available) and Restricted benefit listing for blood glucose monitoring (11 repeats available) |

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| New listing (Minor Submission) | GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS oral liquid, 28 x 250 mL cartons oral liquid, 28 x 250 mL cartons PKU Glytactin [®] RTD 10 PKU Glytactin [®] RTD 15 Cortex Health Pty Ltd | Medicinal food | Restricted benefit listing for phenylketonuria. |
| New listing (Major Submission) | IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig [®] Gilead Sciences Pty Ltd | Chronic lymphocytic leukaemia | To request Authority Required (STREAMLINED) listing for the treatment of chronic lymphocytic leukaemia in patients with progressive disease despite previous treatment. |
| New listing (Major Submission) | IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig [®] Gilead Sciences Pty Ltd | Indolent non-Hodgkin's lymphoma | To request Authority Required (STREAMLINED) listing for the treatment of indolent subtypes of B-cell non-Hodgkin's lymphoma in patients with progressive disease despite previous treatment. |

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| Change to listing (Minor Submission) | IMATINIB 100 mg tablet, 56 400 mg tablet, 28 Glivec [®] Novartis Pharmaceuticals Australia Pty Ltd | Gastrointestinal stromal tumours | To amend the existing maximum quantities applying to each strength to align with the new pack sizes of 28 tablets and 56 tablets in the gastrointestinal stromal tumour listings only. |
| New listing (Major Submission) | INFLUENZA VACCINE (quadrivalent) 0.5 mL pre-filled syringe Fluarix tetra [®] GlaxoSmithKline Australia Pty Ltd | Influenza | To request inclusion of quadrivalent influenza vaccination on the National Immunisation Program's Designated Vaccines List for the prevention of seasonal influenza. |
| New listing (Minor Submission) | INSULIN GLARGINE 100 international units/mL injection, 5 x 3 mL cartridges Basaglar [®] , Basaglar KwikPen [®] Eli Lilly Australia Pty Ltd | Diabetes | To request unrestricted benefit listing |

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| Change to listing (Minor Submission) | IVABRADINE 5 mg tablet, 56 7.5 mg tablet, 56 Coralan [®] Servier Laboratories (Australia) Pty Ltd | Chronic heart failure | To streamline the current Authority Required listing and amend existing Prescriber Instruction to allow resting heart rate to be measured by ECG or echocardiography. |
| Change to listing (Minor Submission) | LACOSAMIDE 50 mg tablet Vimpat [®] UCB Australia Pty Ltd | Epilepsy | To allow continued treatment with the 50 mg strength tablet. |
| New listing (Major Submission) | LEDIPASVIR with SOFOSBUVIR ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 Harvoni [®] Gilead Sciences Pty Ltd | Hepatitis C | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of genotype 1 chronic hepatitis C virus infection in adult patients. |

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| New listing (Major Submission) | LIGNOCAINE 5% patch: dermal, 30 Versatis [®] bioCSL Pty Ltd | Postherpetic neuralgia | To request Authority Required (STREAMLINED) listing for the treatment of patients with postherpetic neuralgia. |
| New listing (Major Submission) | LURASIDONE HYDROCHLORIDE 40 mg tablet, 30 80 mg tablet, 30 Latuda [®] Commercial Eyes Pty Ltd | Schizophrenia | To request Authority Required (STREAMLINED) listing for the treatment of schizophrenia. |
| New listing (Major Submission) | LUTROPIN ALFA 75 IU injection [1 x 75 IU vial] (& inert substance diluent [1 x 1 mL vial], 1 pack Luveris [®] Merck Serono Australia Pty Ltd | Infertility | To request Section 100 (IVF/GIFT program) listing for women who are receiving assisted reproductive medical treatment and have severe luteinising hormone deficiency. |

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| New listing (Major Submission) | NETUPITANT with PALONOSETRON netupitant 300 mg + palonosetron 500 microgram capsule, 1 Akynzeo [®] Specialised Therapeutics Australia Pty Ltd | Nausea and vomiting | To request Authority Required (STREAMLINED) and Section 100 (Efficient Funding of Chemotherapy - Related Benefits) listing for the prevention of nausea and vomiting associated with initial and repeat courses of highly and moderately emetogenic cancer chemotherapy. |
| New listing (Major Submission) | NINTEDANIB 100 mg capsule, 60 150 mg capsule, 60 Ofev [®] Boehringer Ingelheim Pty Ltd | Non-small cell lung cancer | To request Authority Required listing for the treatment of locally advanced, metastatic or recurrent non-small cell lung cancer. |
| New listing (Major Submission) | NINTEDANIB 100 mg capsule, 60 150 mg capsule, 60 Ofev [®] Boehringer Ingelheim Pty Ltd | Idiopathic pulmonary fibrosis | To request Authority Required listing for the treatment of idiopathic pulmonary fibrosis for patients aged 40 years or older. |

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| New listing (Major Submission) | OBINUTUZUMAB 1 g/40 mL injection, 40 mL vial Gazyva [®] Roche Products Pty Ltd | Chronic lymphocytic leukaemia | To request Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of chronic lymphocytic leukaemia. |
| New listing (Minor Submission) | OXYCODONE + NALOXONE oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg tablet: modified release, 28 tablets oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg tablet: modified release, 28 tablets oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg tablet: modified release, 28 tablets Targin [®] Mundipharma Pty Ltd | Pain | To list additional strengths for the same indications currently applying to the existing tablets. |

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| New listing (Minor Submission) | OXYCODONE 5 mg tablet: modified release, 28 Oxycodone Sandoz [®] 5 mg Sandoz Pty Ltd | Pain | To request Restricted benefit listing for chronic severe disabling pain not responding to non-narcotic analgesics. |
| Change to listing (Minor Submission) | PANITUMUMAB 100 mg/5 mL injection, 1 x 5 mL vial 400 mg/20 mL injection, 1 x 20 mL vial Vectibix [®] Amgen Australia Pty Ltd | Metastatic colorectal cancer | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the first-line treatment of RAS wild-type metastatic colorectal cancer in patients meeting certain criteria. |
| New listing (Major Submission) | PEMBROLIZUMAB 50 mg injection: powder for, 1 vial 100 mg injection: powder for, 1 vial Keytruda [®] Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | To request Section 100 (Highly Specialised Drugs) listing for the treatment of unresectable Stage III or Stage IV malignant melanoma. |

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| Change to listing (Major Submission) | PNEUMOCCAL POLYSACCHARIDE CONJUGATE VACCINE (13-valent) 0.5 mL injection Prevenar 13 [®] Pfizer Australia Pty Ltd | Pneumococcal disease | To request an extension of the use of 13-valent pneumococcal vaccine on the National Immunisation Program for the prevention of pneumococcal disease in non-Indigenous adults aged 65 years and Indigenous adults aged 50 years. |
| New listing (Minor Submission) | POSACONAZOLE 100 mg modified release tablet Noxafil [®] Merck Sharp & Dohme (Australia) Pty Ltd | Fungal infections | To request Authority Required listing of a new dose presentation for the same indications as those applying to the oral liquid presentation. |
| New listing (Minor Submission) | PROPRANOLOL 3.75 mg/mL oral liquid, 2 x 120 mL Hemangiol [®] Pierre Fabre Australia Pty Ltd | Infantile hemangioma | To request Authority Required listing for the treatment of proliferating infantile hemangioma requiring systemic therapy. |

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| New listing (Major Submission) | REGORAFENIB 40 mg tablet, 84 Stivarga [®] Bayer Australia Ltd | Gastrointestinal stromal tumours | To request Authority Required (STREAMLINED) listing for the treatment metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate and sunitinib treatment due to resistance or intolerance. |
| New listing (Major Submission) | RIBAVIRIN 400 mg tablet, 28 600 mg tablet, 28 Ibavyr [®] Clinect Pty Ltd | Hepatitis C | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of chronic hepatitis C viral infection (genotype 2 or 3) in combination with sofosbuvir in patients 18 years or older who have compensated liver disease. |
| New listing (Major Submission) | RITUXIMAB 500 mg/50 mL injection: 1 x 50 mL vial MabThera [®] Roche Products Pty Ltd | Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) | To request Section 100 (Highly Specialised Drugs Program) listing for the induction of remission of severe active GPA and MPA in patients who are contraindicated or refractory to cyclophosphamide. |

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|---|---|--|--|
| New listing (Major Submission) | RUXOLITINIB 5 mg tablet, 56 15 mg tablet, 56 20 mg tablet, 56 Jakavi [®] Novartis Pharmaceuticals Australia Pty Ltd | Myelofibrosis | To request Authority Required listing for the treatment of patients with intermediate-2 and high risk myelofibrosis with disease-related symptoms and patients with intermediate-1 risk myelofibrosis who have severe disease-related symptoms and who are intolerant, resistant or refractory to or not candidates for available therapy. |
| New listing (Major Submission) | SECUKINUMAB 150 mg injection: powder for, 1 vial 150 mg/1 mL injection: solution, 1 mL injection device 150 mg/1 mL injection: solution, 1 mL syringe Cosentyx [®] Novartis Pharmaceuticals Australia Pty Ltd | Severe chronic plaque psoriasis | To request Restricted Benefit listing for the treatment of severe chronic plaque psoriasis. |
| New listing (Major Submission) | SOFOSBUVIR 400 mg tablet, 28 Sovaldi [®] Gilead Sciences Pty Ltd | Hepatitis C | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of hepatitis C viral infection. |

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2015 PBAC MEETING**

Closing date for consumer comments 11 February 2015

| Submission type <i>(new listing, change to listing)</i> | Drug Name, form(s), strength(s) and Sponsor <i>(Drug name, form, strength, Trade name[®], Sponsor)</i> | Drug Type and Use <i>(What is the drug used to treat?)</i> | Listing requested by Sponsor / Purpose of Submission <i>(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased)</i> |
|---|---|--|--|
| New listing (Major Submission) | SORAFENIB 200 mg tablet, 60 Nexavar [®] Bayer Australia Ltd | Thyroid cancer | To request Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic progressive radioactive iodine refractory differentiated thyroid cancer. |
| New listing (Minor Submission) | SUNITINIB 37.5 mg capsule, 28 Sutent [®] Pfizer Australia Pty Ltd | Pancreatic neuroendocrine tumours, renal cell carcinoma and gastrointestinal stromal tumours | To request Authority Required listing of a new strength for the same indications as the existing 12.5 mg, 25 mg and 50 mg strengths. |
| New listing (Minor Submission) | TESTOSTERONE 1% gel, 2 x 88 g pump packs Testogel [®] Besins Healthcare Australia Pty Ltd | Androgen deficiency | To list a new form presentation in addition to the current sachet presentation. |

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|---|--|--|---|
| New listing (Major Submission) | TESTOSTERONE 50 mg/mL cream, 50 mL AndroForte [®] 5 Lawley Pharmaceuticals Pty Ltd | Testosterone deficiency | To request Authority Required listing for testosterone replacement therapy for symptomatic testosterone deficient males. |
| New listing (Major Submission) | TOFACITINIB 5 mg tablet, 56 Xeljanz [®] Pfizer Australia Pty Ltd | Severe active rheumatoid arthritis | To request Authority Required listing for the treatment of severe active rheumatoid arthritis. |
| New listing (Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN FORMULA triglycerides medium chain oral liquid, 8 x 500 mL cartons Nutrini Peptisorb [®] Nutricia Australia Pty Ltd | Medicinal food | To request restricted benefit listing for the dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis, gastrointestinal disorders, radioenteritis, chemotherapy or bone marrow transplant. |

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|---|---|--|--|
| Change to listing (Major Submission) | VEDOLIZUMAB 300 mg injection: powder for, 1 vial Entyvio [®] Takeda Pharmaceuticals Australia Pty Ltd | Crohn's disease | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of Crohn's disease. |
| New listing (Major Submission) | VEDOLIZUMAB 300 mg injection: powder for, 1 vial Entyvio [®] Takeda Pharmaceuticals Australia Pty Ltd | Ulcerative colitis | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of moderate to severe ulcerative colitis. |
| Subcommittee report (DUSC Analysis) | Not applicable | Hepatitis B | To examine the utilisation of medicines for the treatment of hepatitis B. |
| Subcommittee report (DUSC Analysis) | Not applicable | Crohn's Disease | To examine utilisation of biological disease-modifying anti-rheumatic drugs (bDMARDs) adalimumab and infliximab for Crohn's disease. |

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|---|---|--|--|
| Subcommittee report (DUSC Analysis) | Not applicable | Pulmonary Arterial Hypertension | To assess the utilisation of medicines for the treatment of pulmonary arterial hypertension (PAH). |
| Other business | Not applicable | Not applicable | To seek PBAC consideration of the draft Managed Access Programme framework which has been developed by the Access to Medicines Working Group. |