

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

Closing date for consumer comments 3 October 2018

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or the National Immunisation Program.

The PBAC agenda consists of the following:

- 1 Minutes of Previous Meeting**
- 2 Chairman's report (verbal)**
- 3 Matters arising from the minutes**
- 4 Matters arising/outstanding**
- 5 New drug applications**
- 6 Requests for changes to listings**
- 7 Resubmissions**
- 8 Pricing Matters**
- 9 Matters relating to PBS review**
- 10 Subcommittee and Working Party reports**
- 11 Other business**
- 12 Correspondence**
- 13 Further information**
- 14 Late papers**
- 15 Tabled papers**

Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and resubmissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.

Pharmaceutical benefits listed in the Schedule fall into three broad categories:

Unrestricted benefits – have no restrictions on their therapeutic uses;

Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and

Authority required benefits – Authority required benefits fall into two categories:

- *Authority required benefits* require prior approval from Medicare Australia or the DVA (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Submissions are categorised broadly as major or minor:

- *Major*: Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
- *Minor*: Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.

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Change to listing (Major Submission)	ALEMTUZUMAB Solution concentrate for I.V. infusion 12 mg in 1.2 mL Lemtrada® Sanofi-Aventis Australia Pty Ltd	Relapsing remitting multiple sclerosis (RRMS)	To request a change to the existing listing to allow for retreatment of RRMS with two additional courses of treatment in patients who have had an initial two courses of treatment.
Change to listing (Minor Submission)	AMINO ACIDS-SYNTHETIC, FORMULA Oral powder 400 g (Neocate Junior Vanilla) Neocate Junior® Vanilla Nutricia Australia Pty Limited	Cow's milk allergy, multiple protein food intolerance and other medical conditions where an elemental diet is required	To request a formulation change to the existing Authority Required listing of Neocate Junior Vanilla.
New listing (Major Submission)	APALUTAMIDE Tablet 60 mg Erlyand® Janssen-Cilag Pty Ltd	Castration resistant prostate cancer	To request an Authority Required listing for the treatment of non-metastatic castration resistant prostate cancer in combination with androgen deprivation therapy.
Change to listing (Major Submission)	BOTULINUM TOXIN TYPE A Lyophilised powder for injection 100 units Botox® Allergan Australia Pty Ltd	Focal spasticity of the lower limb	Resubmission to request an extension to the current Section 100 (Botulinum Toxin Program) listing to include the treatment of lower limb focal spasticity in adults following stroke, who meet certain conditions.

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Change to listing (Minor Submission)	BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris® Takeda Pharmaceuticals Australia Pty Ltd	Cutaneous T-cell lymphomas (CTCL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of refractory or relapsed CD30 positive cutaneous T-cell lymphomas (CTCL).
New listing (Major Submission)	BUPRENORPHINE Injection 8 mg in 0.16 mL pre-filled syringe Injection 16 mg in 0.32 mL pre-filled syringe Injection 24 mg in 0.48 mL pre-filled syringe Injection 32 mg in 0.64 mL pre-filled syringe Injection 64 mg in 0.18 mL pre-filled syringe Injection 96 mg in 0.27 mL pre-filled syringe Injection 128 mg in 0.36 mL pre-filled syringe Buvidal® Camarus AB	Opiate dependence	To request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opiate dependence.
Change to listing (Minor Submission) WITHDRAWN	CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® Ipsen Pty Ltd	Clear cell variant renal cell carcinoma (RCC)	To request an amendment to the current restriction to allow use of cabozantinib in patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal.

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Change to listing (Minor Submission)	CARFILZOMIB Powder for injection 30 mg Powder for injection 60 mg Kyprolis® Amgen Australia Pty Ltd	Multiple myeloma	To request an amendment to the restriction for pomalidomide (sponsored by Celgene Pty Limited) to allow the use of any proteasome inhibitor (bortezomib or carfilzomib) prior to treatment with pomalidomide.
Change to listing (Major Submission)	CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units Dysport® Ipsen Pty Ltd	Spasticity of the lower limb	To extend the current Section 100 (Botulinum Toxin Program) listing to include the treatment of patients with moderate to severe spasticity of the lower limb following an acute event.

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New listing (Major Submission)	CRISABOROLE Ointment containing crisaborole 20 mg per g, 60 g Staquis® Pfizer Australia Pty Ltd	Atopic dermatitis	To request an Authority Required (STREAMLINED) listing for the treatment of mild to moderate atopic dermatitis in patients who have failed to achieve satisfactory disease control with, or are contraindicated to, topical corticosteroids.
New listing (Minor Submission)	DENOSUMAB Injection 120 mg in 1.7 mL Xgeva® Amgen Australia Pty Limited	Multiple myeloma	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of multiple myeloma.

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New listing (Major Submission)	DURVALUMAB Solution for I.V. infusion 120 mg in 2.4 mL Solution for I.V. infusion 500 mg in 10 mL Imfinzi® AstraZeneca Pty Ltd	Non-small cell lung cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Stage III non-small cell lung cancer.
New listing (Major Submission)	ENCORAFENIB and BINIMETINIB Encorafenib: capsule 50 mg capsule 75 mg Binimetinib: tablet 15 mg BRAFTOVI® and MEKTOVI® Pierre Fabre Australia Pty Ltd	Melanoma	To request an Authority Required (STREAMLINED) listing for the concurrent use of encorafenib and binimetinib for the treatment of BRAFV600 mutation positive unresectable Stage III or metastatic (Stage IV) melanoma.
New listing (Major Submission) WITHDRAWN	ERENUMAB Injection 70 mg in 1 mL single dose pre-filled pen Aimovig® Novartis Pharmaceuticals Australia Pty Ltd	Episodic migraine	To request an Authority Required (STREAMLINED) listing for prophylaxis in patients with episodic migraine.

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Change to recommended listing (Minor Submission)	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4; Injections 50 mg in 1 mL single use pre-filled syringes, 4 Brenzys® Merck Sharp & Dohme (Australia) Pty Limited	Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis	To request changes to the current Initial 1, Initial 2 and First Continuing restrictions for Brenzys®, including changing the restriction level to allow telephone authority.
New listing (Minor Submission)	FERRIC CARBOXYMALTOSIDE Injection 1 g (iron) in 20 mL Ferinject® Vifor Pharma Pty Limited	Iron deficiency anaemia	To request an unrestricted benefit listing for a new strength of iron injection.

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Change to listing (Minor Submission)	FLUTICASONE PROPIONATE with EFORMOTEROL Pressurised inhalation containing fluticasone propionate 50 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses; Pressurised inhalation containing fluticasone propionate 125 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses; Pressurised inhalation containing fluticasone propionate 250 micrograms with formoterol fumarate dihydrate 10 micrograms per dose, 120 doses Flutiform® 50/5, 125/5, 250/10 Mundipharma Pty Ltd	Asthma	To request the current Authority Required (STREAMLINED) listing be amended to a Restricted Benefit.
New listing (Minor Submission)	FOLLITROPIN ALFA with LUTROPIN ALFA Injection 900 I.U. - 450 I.U. in 1.44 mL multi-dose cartridge Pergoveris® Merck Serono Australia Pty Ltd	Stimulation of follicular development	To request a Section 100 (IVF program) listing of a new form of follitropin alfa with lutropin alfa.

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New listing (Minor Submission)	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Oral liquid 250 mL, 30 (PKU Glytactin RTD 15 Lite) PKU Glytactin RTD 15 LITE Cortex Health Pty Ltd	Phenylketonuria (PKU)	To request a Restrict Benefit listing for the treatment of PKU.
New listing (Minor Submission)	GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE Sachets containing oral powder 33.3 g, 16 (PKU GMPPro) PKU GMPPro Nutricia Australia Pty Limited	Phenylketonuria (PKU)	To request a Restricted Benefit listing for the treatment of PKU.
Change to listing (Minor Submission)	HYPROMELLOSE Eye drops 3 mg per mL, 10 mL In a Wink Moisturising®, Genteal® Alcon Laboratories (Australia) Pty Ltd	Severe dry eye syndrome, including Sjogren's syndrome	To request a change in pack size for the In a Wink Moisturising® and Genteal® brands of hypromellose.

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Change to listing (Major Submission)	INACTIVATED QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION) Injection 0.5mL in pre-filled syringe Afluria® Quad Seqirus Australia Pty Ltd	Prevention of seasonal influenza	To extend the current National Immunisation Program (NIP) listing to include persons aged 5-17 years who are currently eligible for vaccination through the NIP with other brands of influenza vaccine.
New listing (Major Submission)	INOTUZUMAB OZOGAMICIN Powder for I.V. infusion 1 mg Besponsa® Pfizer Australia Pty Ltd	Acute lymphoblastic leukaemia (ALL)	To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of relapsed or refractory CD22 positive B-cell precursor acute lymphoblastic leukaemia (ALL).
New listing (Major Submission)	INSULIN ASPART Injections (human analogue), pre filled pen, 100 units per mL, 3mL Injections (human analogue), vial, 100 units per mL, 10 mL Injections (human analogue), cartridges, 100 units per mL, 3 mL Fiasp® Novo Nordisk Pharmaceuticals Pty Ltd	Diabetes Mellitus	To request an unrestricted benefit listing for diabetes mellitus.

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New listing (Minor Submission)	ISOTRETINOIN Capsule 5 mg Oratane® Oraderm Pharmaceuticals Pty Ltd	Severe cystic acne	To request an Authority Required (STREAMLINED) listing of a new strength of isotretinoin for the treatment of severe cystic acne.
Change to listing (Major Submission)	LACOSAMIDE Tablet 50 mg Tablet 100 mg Tablet 150 mg Tablet 200 mg Oral liquid 10 mg per mL, 200 mL Vimpat® UCB Pharmaceuticals Pty Ltd	Partial epileptic seizures	To request an Authority Required (STREAMLINED) listing for the treatment of intractable partial epileptic seizures for patients aged 4 to 15 years.
New listing (Minor Submission)	LENVATINIB Capsule 4 mg (as mesilate) Lenvima® Eisai Australia Pty Ltd	Hepatocellular carcinoma	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable hepatocellular carcinoma.

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New listing (Minor Submission)	NIVOLUMAB and 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® and Yervoy® 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 the concurrent use of nivolumab and ipilimumab for the treatment of Stage IV clear cell variant renal cell carcinoma (RCC).
New listing (Major Submission)	OBETICHOLIC ACID Tablet 5 mg Tablet 10 mg Ocaliva® Emerge Health Pty Ltd	Primary biliary cholangitis	To request an Authority Required (STREAMLINED) listing for the treatment of patients with primary biliary cholangitis.

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New listing (Minor Submission)	OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® Astra Zeneca Pty Ltd	Non-small cell lung cancer (NSCLC)	Resubmission to request an Authority Required listing for the treatment of patients with locally advanced or metastatic epidermal growth factor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC) who have progressed on or after prior treatment with an EGFR tyrosine kinase inhibitor (TKI).
New listing (Minor Submission)	PEGFILGRASTIM Injection 6 mg in 0.6 mL single use pre-filled syringe Fulphila® Alphapharm Pty Ltd	Chemotherapy-induced neutropenia	Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required (STREAMLINED) listing of this biosimilar brand for all indications for which the reference biologic is currently PBS listed.
Change to listing (Minor Submission)	PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Melanoma	To request removal of the weight-based dosing option for pembrolizumab in unresectable stage III or Stage IV malignant melanoma.

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Change to listing (Major Submission)	PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Melanoma	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as an adjuvant to complete surgical resection for Stage III or Stage IV malignant melanoma.
Change to listing (Major Submission)	PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, in combination with platinum chemotherapy and pemetrexed, for the treatment of EGFR wildtype ALK translocation negative non-squamous NSCLC.
Change to listing (Major Submission)	PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Primary mediastinal B-cell lymphoma (PMBCL)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with relapsed or refractory PMBCL who meet certain conditions.

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Change to listing (Major Submission)	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 13-VALENT ADSORBED Injection 0.5 mL in pre-filled syringe Prevenar-13® Pfizer Australia Pty Ltd	Prevention of pneumococcal disease	To expand the current National Immunisation Program (NIP) listing to include: - children aged 5 to 14 years; - adults aged 15 to 64 years with increased risk of pneumococcal disease; and - Aboriginal and Torres Strait Islander adults aged 25 years and older.
Change to listing (Minor Submission)	PONATINIB Tablet 15 mg (as hydrochloride) Tablet 45 mg (as hydrochloride) Iclusig® Specialised Therapeutics Australia Pty Ltd	Chronic myeloid leukaemia (CML)	To request amendments to the circumstances under which ponatinib is subsidised for the treatment of CML.
New listing (Major Submission)	REGORAFENIB Tablet 40 mg (as monohydrate) Stivarga® Bayer Australia Ltd	Hepatocellular carcinoma (HCC)	Resubmission 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)	RILUZOLE Oral liquid 50 mg per 10 mL, 300 mL Teglutik® Seqirus (Australia) Pty Ltd	Amyotrophic lateral sclerosis (ALS)	To request an Authority Required listing of an oral liquid form of riluzole for the treatment of ALS.

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Change to listing (Major Submission)	RIVAROXABAN Tablet 10 mg Xarelto® Bayer Australia Ltd	Venous thromboembolism	To request an Authority Required (STREAMLINED) listing for the prevention of recurrent venous thromboembolism.
New listing (Major Submission)	ROMOSOZUMAB Injection 105 mg in 1.17 mL pre-filled pen Injection 105 mg in 1.17 mL pre-filled syringe Evenity® Amgen Australia Pty Ltd	Osteoporosis	To request an Authority Required listing for the treatment of patients with severe osteoporosis.
New listing (Major Submission)	SAFINAMIDE Tablet 50 mg Tablet 100 mg Xadago® Seqirus Australia Pty Ltd	Parkinson disease	To request a restricted benefit listing for the treatment of patients with Parkinson disease, as add-on therapy to a regimen that includes levodopa, in patients experiencing motor fluctuations.
Change to listing (Minor Submission)	SAPROPTERIN Tablet (soluble) containing sapropterin dihydrochloride 100 mg Kuvan® BioMarin Pharmaceutical Australia Pty Ltd	Hyperphenylalaninemia (HPA)	Resubmission to request an Authority Required listing for the treatment of HPA in patients with phenylketonuria.

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New listing (Major Submission)	SARILUMAB Injection 200 mg in 1.14 mL pre-filled syringe Injection 150 mg in 1.14 mL pre-filled syringe Kevzara® Sanofi-Aventis Australia Pty Ltd	Rheumatoid arthritis	To request an Authority Required listing for the treatment of patients with severe active rheumatoid arthritis.
Change to listing (Minor Submission)	SEASONAL INFLUENZA VACCINES Injection 0.5 mL in pre-filled syringe Afluria® Quad FluQuadri® Fluarix Tetra® Seqirus (Australia) Pty Ltd Sanofi-Aventis Australia Pty Ltd GlaxoSmithKline Australia Pty Ltd	Prevention of seasonal influenza	To request listing of seasonal influenza vaccines on the National Immunisation Program (NIP) for Aboriginal and Torres Strait Islander children and adolescents aged 5 - 14 years.
New listing (Major Submission)	TESTOSTERONE Transdermal gel (pump pack) 23 mg per 1.15 g dose, 56 doses Testavan® Ferring Pharmaceuticals Pty Ltd	Androgen deficiency; Micropenis; Pubertal induction; Constitutional delay of growth or puberty	To request an Authority Required listing for the treatment of male hypogonadism.

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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	Asthma	Resubmission to extend the current Authority Required (STREAMLINED) listing to include treatment of severe asthma for children and adolescents aged 6 to 17 years.
Change to listing (Major Submission)	TOCILIZUMAB Injection 162 mg in 0.9 mL pre-filled pen Injection 162 mg in 0.9 mL pre-filled syringe Actemra® Roche Products Pty Ltd	Giant Cell Arteritis	To request an Authority Required listing for the treatment of giant cell arteritis.
Change to listing (Major Submission)	TOFACITINIB Tablet 5 mg Xeljanz® Pfizer Australia Pty Ltd	Psoriatic arthritis	To request an Authority Required listing for the treatment of patients with severe active psoriatic arthritis who have had an inadequate response to methotrexate and disease modifying anti-rheumatic drugs.

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New listing (Major Submission)	VARICELLA ZOSTER RECOMBINANT VACCINE Injection [1 vial] (& adjuvant substance diluent [0.5 mL vial], 1 pack Shingrix® GlaxoSmithKline Australia Pty Ltd	Prevention of herpes zoster	To request National Immunisation Program (NIP) listing for the prevention of herpes zoster in adults aged 60 years with a 5 year catch-up program for persons aged over 60 years.
New listing (Major Submission)	VENETOCLAX Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd	Relapsed or refractory chronic lymphocytic leukaemia	To request an Authority Required listing, in combination with rituximab, for the treatment of patients with relapsed or refractory CLL who are unsuitable for treatment with a purine analogue.
Subcommittee report (DUSC Analysis Submission)	BEVACIZUMAB Avastin® Roche Products Pty Ltd	Advanced Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer	To compare the predicted and actual use of bevacizumab for Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer since PBS listing for these indications.

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

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Subcommittee report (DUSC Analysis Submission)	Daclatasvir Grazoprevir with elbasvir Ledipasvir with sofosbuvir Paritaprevir with ritonavir with ombitasvir and dasabuvir and ribavirin Ribavirin Sofosbuvir Sofosbuvir with velpatasvir Peginterferon alfa-2a Daklinza® Zepatier® Harvoni® Viekira Pak-RBV® Sovaldi® Epclusa® Pegasys® AbbVie Pty Ltd Bristol-Myers Squibb Australia Pty Ltd Clinect Pty Ltd Gilead Sciences Pty Limited Merck Sharp & Dohme (Australia) Pty Ltd Roche Products Pty Ltd	Chronic hepatitis C infection	To review the use of direct acting antiviral medicines listed on the PBS for the treatment of chronic hepatitis C infection.

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Subcommittee report (DUSC Analysis Submission)	FEBUXOSTAT Adenuric® A. Menarini Australia Pty Limited	Chronic gout	To compare the predicted and actual use of febuxostat for the treatment of chronic gout since PBS listing.
Subcommittee report (DUSC Analysis Submission)	RUXOLITINIB Jakavi® Novartis Pharmaceuticals Australia Pty Limited	Myelofibrosis	To compare the predicted and actual use of ruxolitinib for intermediate-1, intermediate-2 and high risk myelofibrosis since PBS listing.
PBS review (Other Submission)	Post-market Review of Pulmonary Arterial Hypertension (PAH) Medicines Bosentan Ambrisentan Macitentan Epoprostanol Iloprost Sildenafil Tadalafil Riociguat (all listed brands)	Pulmonary Arterial Hypertension	To consider the findings of the Post-Market Review of PBS medicines for Pulmonary Arterial Hypertension (PAH).