

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2020 PBAC MEETING**

Closing date for consumer comments is 12 February 2020

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 the Department of Human Services (DHS) or the Department of Veterans' Affairs (DVA) (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from DHS or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Submissions are categorised broadly as major or minor:

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

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New listing (Major Submission)	ACALABRUTINIB Capsule 100 mg Calquence® AstraZeneca Pty Ltd	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)	To request an Authority Required listing for the treatment of patients with relapsed or refractory CLL or SLL considered unsuitable for treatment with a purine analogue.
New listing (Minor Submission)	ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled syringe, 2 Injection 40 mg in 0.8 mL pre-filled pen, 2 Injection 40 mg in 0.8 mL pre-filled syringe, 6 Injection 40 mg in 0.8 mL pre-filled pen, 6 Hyrimoz® Sandoz Pty Ltd	Crohn disease Ulcerative colitis Juvenile idiopathic arthritis Fistulising Crohn disease Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Chronic plaque psoriasis Hidradenitis suppurativa	To request an Authority Required listing of a biosimilar adalimumab under the same conditions as the reference biologic.
Change to recommended listing (Minor Submission)	ALIROCUMAB Injection 75 mg in 1 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Praluent® Sanofi-aventis Australia Pty Ltd	Hypercholesterolaemia	Resubmission to request an Authority Required listing for the treatment of hypercholesterolaemia in patients with atherosclerotic cardiovascular disease and additional high-risk factors.

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Change to listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Sachets containing oral powder 27.8 g, 30 PKU Lophlex® Nutricia Australia Pty Ltd	Phenylketonuria (PKU)	To request a formulation change to PKU Lophex® for the dietary management of patients with PKU.
Change to listing (Minor Submission)	AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS Oral powder 400 g Neocate LCP® AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS Oral powder 400 g Neocate Syneo® Nutricia Australia Pty Ltd	Cow's milk allergy, multiple food intolerance and other medical conditions where an amino acid-based formula is recommended	To request a formulation change to Neocate LCP® and Neocate Syneo® for the dietary management of patients with Cow's milk allergy, multiple food intolerance and other medical conditions where an amino acid-based formula is recommended.
Change to listing (Minor Submission)	A POMORPHINE Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL,	Parkinson disease	To request General Schedule, Authority Required (STREAMLINED) listings of apomorphine for the continuing treatment of Parkinson Disease for patients who meet certain conditions, following initiation with the current Section 100 (Highly Specialised Drugs Program) listings.

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	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen Apomine solution for infusion®; Apomine Intermittent® Pfizer Australia Pty Ltd		
Change to listing (Major Submission)	ATEZOLIZUMAB Solution concentrate for I.V. infusion 840 mg in 14 mL Tecentriq® Roche Products Pty Ltd	Breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer who are programmed death-ligand 1 (PD-L1)-positive.
Change to recommended listing (Minor Submission)	ATEZOLIZUMAB Solution concentrate for I.V. infusion 840 mg in 14 mL Tecentriq® Roche Products Pty Ltd	Small cell lung cancer (SCLC)	To request listing of an additional vial size for the treatment of patients with extensive stage SCLC and to amend the recommended dosing regimens of atezolizumab for SCLC to allow clinician choice of either 1,200 mg every 3 weeks (Q3W) or 1,680 mg every 4 weeks (Q4W) dosing.
Change to listing (Major Submission)	AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mL Bavencio® Merck Healthcare Pty Ltd	Renal cell carcinoma (RCC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED), in combination with axitinib, for the first-line treatment of patients with Stage IV clear cell variant RCC.

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New listing (Minor Submission)	BENRALIZUMAB Injection 30 mg in 1 mL pre-filled pen Fasenra Pen® AstraZeneca Pty Ltd	Eosinophilic asthma	To request listing of an autoinjector presentation of benralizumab under the same conditions as the current pre-filled syringe.
New listing (Major Submission)	BEZLOTOXUMAB Solution concentrate for I.V. infusion 1000 mg in 40 mL Zinplava® Merck Sharp & Dohme (Australia) Pty Ltd	Prevention of recurrent clostridium difficile infection (CDI)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for prevention of recurrent CDI in patients with confirmed toxin B positive CDI and one or more risk factors for CDI recurrence.
New listing (Minor Submission)	BROLUCIZUMAB Solution for intravitreal injection 19.8 mg in 0.165 mL pre-filled syringe Beovu® Novartis Pharmaceuticals Australia Pty Limited	Subfoveal choroidal neovascularisation (CNV)	Resubmission to request an Authority Required listing for the treatment of patients with CNV due to age-related macular degeneration.
New listing (Minor Submission)	BUPRENORPHINE + NALOXONE Tablet (sublingual) containing 0.7 mg buprenorphine hydrochloride with 0.18 mg naloxone hydrochloride Tablet (sublingual) containing 1.4 mg buprenorphine hydrochloride and	Opiate dependence	Resubmission to request a Section 100 (Opiate Dependence Treatment Program) Restricted Benefit listing for the treatment of patients with opiate dependence.

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	0.36 mg naloxone hydrochloride Tablet (sublingual) containing 2.9 mg buprenorphine hydrochloride and 0.71mg naloxone hydrochloride Tablet (sublingual) containing 5.7 mg buprenorphine hydrochloride and 1.4 mg naloxone hydrochloride Tablet (sublingual) containing 8.6 mg and 2.1mg naloxone hydrochloride Tablet (sublingual) containing 11.4 mg buprenorphine hydrochloride and 2.9 mg naloxone hydrochloride Zubsolv® Mundipharma Pty Ltd		
Change to listing (Major Submission)	CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® Ipsen Pty Ltd	Renal cell carcinoma (RCC)	Resubmission to request an extension to the current Authority Required (STREAMLINED) listing for the treatment of Stage IV clear cell variant RCC to include patients who have not been previously treated with a tyrosine kinase inhibitor (TKI).
New listing (Major Submission)	DINUTUXIMAB BETA Solution concentrate for I.V. infusion 20 mg in 4.5 mL Qarziba® EUSA Pharma (UK) Ltd	Neuroblastoma	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with high risk neuroblastoma or relapsed or refractory neuroblastoma.

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New listing (Major Submission)	DUPILUMAB Injection 300 mg in 2 mL single use pre-filled syringe Dupixent® Sanofi-aventis Australia Pty Ltd	Atopic dermatitis	Resubmission to request an Authority Required listing for the treatment of patients with chronic, severe, atopic dermatitis who have had an inadequate response to topical therapies.
New listing (Major Submission)	ENTRECTINIB Capsule 200 mg Rozlytrek® Roche Products Pty Ltd	Non-small cell lung cancer (NSCLC)	To request an Authority Required listing for the treatment of patients with locally advanced (Stage IIIB) or metastatic (Stage IV) c-ros proto-oncogene 1 (ROS1)-positive NSCLC.
New listing (Major Submission)	FLUOCINOLONE ACETONIDE Intravitreal injection 190 micrograms Iluvien® Specialised Therapeutics Pharma Pty Ltd	Diabetic macular oedema	To request an Authority Required listing for the treatment of patients with diabetic macular oedema who have had an inadequate response to corticosteroids.
Change to listing (Minor Submission)	LISDEXAMFETAMINE Capsule containing lisdexamfetamine dimesilate 20mg Capsule containing lisdexamfetamine dimesilate 30mg Capsule containing lisdexamfetamine dimesilate 40mg Capsule containing lisdexamfetamine	Attention deficit hyperactivity disorder (ADHD)	To request removal of the age of diagnosis criterion from the Authority Required listings of lisdexamfetamine for the treatment of ADHD.

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	dimesilate 50mg Capsule containing lisdexamfetamine dimesilate 60mg Capsule containing lisdexamfetamine dimesilate 70mg Vyvanse® Shire Australia Pty Limited		
New Listing (Minor Submission)	MEPOLIZUMAB Injection 100 mg in 1 mL pre-filled pen Injection 100 mg in 1 mL pre-filled syringe Nucala® GlaxoSmithKline Australia Pty Ltd	Eosinophilic asthma	To request listing of pre-filled syringe and pre-filled pen presentations of mepolizumab under the same conditions as mepolizumab powder for injection 100 mg.
Change to listing (Minor Submission)	MESALAZINE Suppository 1 g Sachet containing granules, 1 g per sachet Pentasa® Ferring Pharmaceuticals Pty Ltd	Ulcerative proctitis Ulcerative colitis Crohn disease	To request a change to the maximum quantity for the 1 g suppository (from 30 to 28 units) and 1 g sachet containing granules (from 120 to 100 sachets) forms of the Pentasa® brand of mesalazine, in line with changes to the pack sizes.

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New listing (Minor Submission)	METHYLPHENIDATE Capsule containing methylphenidate hydrochloride 60 mg (modified release) Ritalin LA® Novartis Pharmaceuticals Australia Pty Limited	Attention deficit hyperactivity disorder (ADHD)	To request an Authority Required listing of a new strength of modified release methylphenidate for the treatment of patients with ADHD.
Change to listing (Minor Submission)	MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE Oral powder 225 g Carbohydrate Free Mixture® Nutricia Australia Pty Ltd	Ketogenic diet	To request a formulation change to Carbohydrate Free Mixture for the dietary management of patients requiring a ketogenic diet.
New listing (Major Submission)	NABIXIMOLS Oromucosal spray, 8 mg per dose, 90 doses Sativex® Emerge Health Pty Ltd	Multiple sclerosis (MS) related spasticity	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe spasticity due to MS who have had an inadequate response to other anti-spasticity medication.

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Change to listing (Minor Submission)	OLAPARIB Capsule 50 mg Tablet 100 mg Tablet 150 mg Lynparza® AstraZeneca Pty Ltd	High grade serous ovarian cancer High grade serous fallopian tube cancer High grade serous primary peritoneal cancer	Resubmission to request the current Authority Required (STREAMLINED) listings for the treatment of patients with high grade serous ovarian, fallopian tube or primary peritoneal cancer be amended to include somatic BRCA 1/2 mutation testing as an option to determine eligibility for treatment.
New listing (Major Submission)	OZANIMOD Capsule 230 micrograms Capsule 460 micrograms Capsule 920 micrograms Zeposia® Celgene Pty Ltd	Relapsing-remitting multiple sclerosis (RRMS)	To request an Authority Required listing for the treatment of patients with RRMS.
New listing (Minor Submission)	PEGFILGRASTIM Injection 6 mg in 0.6 mL single use pre-filled syringe Pelgraz® Accord Healthcare Pty Ltd	Chemotherapy-induced neutropenia	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a biosimilar pegfilgrastim under the same conditions as the reference biologic.

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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 an extension of the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable Stage III or IV malignant melanoma to allow use as a first-line therapy in patients who are BRAF V600 mutation positive.
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)	Resubmission 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.
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 Non-small cell lung cancer (NSCLC)	To request amending the recommended dosing regimens of pembrolizumab for melanoma or NSCLC to allow clinician choice of either 200 mg every 3 weeks (Q3W) or 400 mg every 6 weeks (Q6W) dosing.

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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	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage IIIB-D malignant melanoma.
Change to listing (Major Submission)	PERTUZUMAB Solution for I.V. infusion 420 mg in 14 mL Perjeta® Roche Products Pty Limited	Breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with trastuzumab and chemotherapy, for the neoadjuvant treatment of patients with human epidermal growth factor receptor-2 positive (HER2+) locally advanced, inflammatory or early stage breast cancer.
New listing (Major Submission)	PLITIDEPSIN Powder for I.V. infusion 2 mg with 4 mL solvent Aplidin® Specialised Therapeutics Pharma Pty Ltd	Multiple myeloma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with dexamethasone, for the treatment of patients with relapsed or refractory multiple myeloma who meet certain conditions.

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New listing (Minor Submission)	PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRANSFORMING GROWTH FACTOR BETA-2 Powder for oral liquid, 400 g, 12 Modulen IBD® Nestle Health Science	Crohn disease	To request a Restricted Benefit listing of Modulen IBD for the dietary management of Crohn disease in patients aged 5 years or older in the active or remission phase of disease.
New listing (Major Submission)	RIVAROXABAN Tablet 2.5 mg Xarelto® Bayer Australia	Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients at high risk of recurrent cardiovascular events with CAD or PAD who meet certain conditions.
New listing (Major Submission)	ROMOSUZUMAB Injection 105 mg in 1.17 mL single use pre-filled syringe Evenity® Amgen Australia Pty Ltd	Osteoporosis	Resubmission to request an Authority Required listing for the treatment of patients with severe osteoporosis.

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New listing (Minor Submission)	SEMAGLUTIDE Injection 2 mg in 1.5 mL pre-filled syringe Injection 4 mg in 3 mL pre-filled syringe Ozempic® Novo Nordisk Pharmaceuticals Pty Ltd	Type 2 diabetes mellitus (T2DM)	Resubmission to request the PBAC review its advice on the therapeutic relativities and equi-effective doses of semaglutide and dulaglutide as part its November 2019 recommendation for semaglutide for use in combination with metformin and/or a sulfonylurea for the treatment of patients with T2DM.
New listing (Minor Submission) Consideration suspended – Re-categorised to major submission category under the <i>National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009</i> .	SIPONIMOD Tablet 250 micrograms Tablet 2 mg Mayzent® Novartis Pharmaceuticals Australia Pty Limited	Multiple sclerosis (MS)	Resubmission to request an Authority Required listing for the treatment of patients with a history of relapsing forms of MS who meet certain conditions.

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New listing (Major Submission)	STIRIPENTOL Capsule 250 mg Capsule 500mg 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 adjunctive treatment of patients with generalised tonic-clonic and clonic seizures associated with SMEI (Dravet syndrome) who meet certain conditions.
Change to listing (Minor Submission)	TOCILIZUMAB Injection 162 mg in 0.9 mL single use prefilled pen Injection 162 mg in 0.9 mL single use prefilled syringe Actemra® Roche Products Pty Ltd	Systemic juvenile idiopathic arthritis (sJIA)	To request an extension of the current Authority Required listing of subcutaneous tocilizumab to include the treatment of patients with sJIA.
Change to recommended listing (Minor Submission)	TOFACITINIB Tablet 5 mg Xeljanz® Pfizer Australia Pty Ltd	Chronic plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ulcerative colitis	To request that the PBAC review its advice on the interchangeability of tofacitinib on an individual patient basis with other biological disease modifying antirheumatic drugs under Section 101(3BA) of the <i>National Health Act 1953</i> .

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Change to listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER Oral powder 400 g Duocal® Nutricia Australia Pty Ltd	Proven inborn errors of protein metabolism	To request a formulation change to Duocal for the dietary management of patients with proven inborn errors of metabolism.
Change to listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral powder 400 g Lipistart® Vitaflo Australia Pty Ltd	Dietary management of conditions requiring a source of medium chain triglycerides	To request a formulation change to Lipistart for the dietary management of patients with fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders.
Change to listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral powder 400 g Peptamen Junior® Nestle Health Science	Dietary management of conditions requiring a source of medium chain triglycerides	To request an extension of the current Restricted Benefit listing to include critically or chronically ill paediatric patients who are dependent on nutritional support therapy.
Change to listing (Major Submission)	VENETOCLAX Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg Tablet 10 mg Tablet 50 mg	Chronic lymphocytic leukaemia (CLL)	To request an Authority Required (STREAMLINED) listing, in combination with obinutuzumab, for the first-line treatment of patients with CLL who have coexisting conditions and are unsuitable for fludarabine based chemotherapy.

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	Tablet 100 mg Venclexta® AbbVie Pty Ltd		
Change to listing (Minor Submission)	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE Oral powder 400 g, 6 Sachets containing oral powder 100 g, 10 Renastart® Vitaflo Australia Pty Ltd	Chronic kidney disease (CKD)	To request a formulation change to Renastart for the dietary management of eligible paediatric patients with CKD.
Subcommittee report (DUSC Analysis)	Alemtuzumab Lemtrada® Sanofi-aventis Australia Pty Ltd	Relapsing-Remitting Multiple Sclerosis (RRMS)	To compare the predicted and actual utilisation of alemtuzumab for RRMS since it was PBS listed for this indication.

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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.)
Subcommittee report (DUSC Analysis)	Opioid analgesics All brands and strengths Various sponsors	Analgesia	To assess the utilisation of PBS listed opioid analgesics.
Subcommittee report (DUSC Analysis)	Nintedanib; Pirfenidone Ofev; Esbriet® Boehringer Ingelheim Pty Ltd; Roche Products Pty Ltd	Idiopathic pulmonary fibrosis (IPF)	To compare the predicted and actual utilisation of nintedanib and pirfenidone for the treatment of IPF since PBS listing.
Subcommittee report (DUSC Analysis)	Testosterone Testosterone undecanoate Various brands Various sponsors	Treatment of androgen deficiency both with and without established pituitary or testicular disorders	To assess the impact of restriction changes that have occurred since the previous DUSC analysis in 2015.