PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2014 PBAC MEETING

Closing date for consumer comments 12 February 2014

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 *(new drug application, changes to listings, resubmissions)*	**Drug Name, form(s), strength(s) and Sponsor** *(Drug name, form, strength, Trade name®, Sponsor)*	**Drug Type and Use** *(What is the drug used to treat?)*	**Listing requested by Sponsor / Purpose of Submission** *(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased*
New Listing (Major submission)	ACLIDINIUM BROMIDE, 400 microgram/actuation inhalation: powder for, 60 actuations Bretaris® Genuair® A.Menarini Australia Pty Ltd	Chronic Obstructive Pulmonary Disease (COPD)	To request Restricted Benefit General Schedule listing for patients with chronic obstructive pulmonary disease (COPD).
Re-submission (Major submission)	AFLIBERCEPT, 2 mg/0.05 mL injection, 1 x 0.05 mL vial and 2 mg/0.05 mL injection, 1 x 0.05 mL syringe Eylea® Bayer Australia Ltd	Macular Oedema secondary to central retinal vein occulsion	Re-submission to request Authority required General Schedule listing for the treatment of macular oedema following central retinal vein occlusion (CRVO).
New Listing (Minor submission)	ALENDRONATE + COLECALCIFEROL + CALCIUM, alendronate 70 mg + colecalciferol 140 microgram tablet [4 tablets] (&) calcium (as carbonate) 500 mg tablet [24 tablets], 1 pack Fosamax Plus D-Cal® Merck Sharp and Dohme (Australia) Pty Ltd	Osteoporosis	To request listing as General Schedule Authority Required (STREAMLINED) benefit of a new presentation of alendronate + colecalciferol + calcium.
Change to Listing (Minor submission)	ATOMOXETINE, 10 mg capsule, 28, 18 mg capsule, 28, 25 mg capsule, 28, 40 mg capsule, 28, and 60 mg capsule, 28 Strattera® Eli Lilly Australia Pty Limited	Attention Deficit Hyperactivity Disorder	To request that the current Authority Required listing for atomoxetine be changed to authority required (STREAMLINED) and the restriction wording be altered.

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New Listing (Major submission)	BETAINE, 1 g/g oral liquid: powder for, 180 g Cystadane® Emerge Health Pty Ltd	Homocystinuria	To request an Authority Required General Schedule listing for the treatment of patients with homocystinuria.
Re-submission (Minor submission)	BEVACIZUMAB, 100 mg/4 mL injection, 1 x 4mL vial and 400 mg/16 mL injection, 1x16 mL vial Avastin® Roche Products Pty Limited	Advanced epithelial ovarian, fallopian tube, and primary peritoneal cancer	To request listing as a Section 100 (Efficient Funding of Chemotherapy Program) +/- STREAMLINED benefit for the first-line treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer.
New Listing (Minor submission)	BIMATOPROST + TIMOLOL, bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4mL Ganfort PF® Allergan Australia Pty Ltd	Glaucoma	To request listing of a new preservative free formulation as a restricted benefit within the general and optometrist schedules for the treatment of glaucoma.
New Listing (Major submission)	BRENTUXIMAB VEDOTIN, 50 mg injection, 1 x 50 mg vial Adcetris® Takeda Pharmaceutical Australia Pty Ltd	Systemic Anaplastic Large Cell Lymphoma (sALCL)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (+/- STREAMLINED) listing for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL) who are suitable for further systemic curative-intent salvage therapy.
New Listing (Minor submission)	CALCIUM, tablet (chewable) 500 mg (as carbonate), 60 Cal-500® Petrus Pharmaceuticals Pty Ltd	Hyperphosphataemia associated with chronic renal failure	To request General Schedule Authority Required (STREAMLINED) listing for the treatment of hyperphosphataemia associated with chronic renal failure.
Change to Listing (Major submission)	CERTOLIZUMAB PEGOL, 200 mg/mL injection, 2 x 1 mL syringes Cimzia® UCB Australia Pty Ltd	Ankylosing Spondylitis	To request Authority Required General Schedule listing for the treatment of adults with active ankylosing spondylitis (AS) who meet certain criteria.

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Change to Listing (Minor submission)	CORIFOLLITROPIN ALFA, 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe Elonova® Merck Sharp and Dohme (Australia) Pty Ltd	Assisted reproductive therapies	To request removal of the maximum weight restriction wording from the PBS restriction of Elonova 100 microgram presentation.
Re-submission (Minor submission)	CRIZOTINIB, 200 mg capsule, 60 and 250 mg capsule, 60 Xalkori® Pfizer Australia Pty Ltd	Non-small cell lung cancer (NSCLC)	A resubmission to request Authority Required listing for treatment of a patient with Anaplastic Lymphoma Kinase (ALK) positive non-small cell lung cancer (NSCLC) who meets certain criteria.
Re-submission (Major submission)	ECULIZUMAB, 300 mg/30 mL injection, 1 x 30mL vial Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	Atypical Haemolytic Uraemic Syndrome (aHUS)	Re-submission to request Section 100 (Highly Specialised Drugs Program) or LSDP listing for atypical Haemolytic Uraemic Syndrome (aHUS).
Re-submission (Major submission)	ERLOTINIB, 25 mg tablet, 30, 100 mg tablet, 30 and 150 mg tablet, 30 Tarceva® Roche Products Pty Limited	Lung Cancer	To request that the current Authority Required General Schedule listing for patients with locally advanced or metastatic (stage IIIB or IV) epidermal growth factor (EGFR) wild-type or unknown non-small cell lung cancer (NSCLC) who have progressed on prior platinum therapy and have reached a point where further cytotoxic therapy is not an option, is retained.
Re-submission (Minor submission)	EVEROLIMUS, 5 mg tablet, 30 and 10 mg tablet, 30 Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Malignant pancreatic neuroendocrine tumour (pNET)	To request a General Schedule Authority Required listing for the treatment of metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine temour (pNET).
Re-submission (Minor submission)	EVEROLIMUS, 5 mg tablet, 30 and 10 mg tablet, 30 Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Clear cell variant renal cell carcinoma	To request a General Schedule Authority Required listing for the treatment of Stage IV clear cell variant renal cell carcinoma after progression on sunitinib.

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Re-submission (Major submission)	FAMPRIDINE, 10 mg tablet: modified release, 56 tablets Fampyra® Biogen Idec Australia Pty Ltd	Multiple Sclerosis	Resubmission to request an Authority Required General Schedule listing for the treatment for the symptomatic improvement of walking ability of an ambulatory patient with clinically definite multiple sclerosis who meets certain criteria.
New Listing (Major submission)	FEBUXOSTAT, 80 mg tablet, 28 and 120 mg tablet, 28 Adenuric® A.Menarini Australia Pty Ltd	Gout	To request Authority Required (STREAMLINED) General Schedule listing for the treatment of chronic gouty arthritis associated with hyperuricaemia.
New Listing (Major submission)	FENTANYL, 100 microgram tablet: sublingual, 10 and 30, 200 microgram tablet: sublingual, 10 and 30 and 400 microgram tablet: sublingual, 10 and 30 Abstral® A.Menarini Australia Pty Ltd	Palliative Care	To request Authority Required listing on the palliative care schedule for the management of breakthrough pain in patients with cancer who are already receiving maintenance opioid therapy for chronic pain and are unable to tolerate further escalation of morphine for breakthrough pain.
New Listing (Major submission)	FENTANYL, 100 micrograms/actuation nasal spray, 8 actuations and 400 micrograms/actuation nasal spray, 8 actuations PecFent® AstraZeneca Pty Ltd	Palliative Care	Resubmission to request Authority Required listing on the palliative care schedule for the management of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic pain and are unable to tolerate further escalation of morphine for breakthrough pain.
New Listing (Major submission)	FLUTICASONE FUROATE AND VILANTEROL TRIFENATATE, fluticasone furoate 100 microgram/actuation + vilanterol trifenatate 25 microgram/actuation, inhalation: powder for, 30 actuations Dry powder inhaler (DPI) Breo® Ellipta® GlaxoSmithKline Australia Pty Ltd	Chronic Obstructive Pulmonary Disease (COPD)	To request a Restricted Benefit General Schedule listing for the symptomatic treatment of chronic obstructive pulmonary disease (COPD), where FEV_1 is less than 50% of predicted normal and there is a history of repeated exacerbations despite regular beta-2 agonist bronchodilator therapy.

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New Listing (Major submission)	FLUTICASONE FUROATE AND VILANTEROL TRIFENATATE, fluticasone furoate 100 microgram/actuation + vilanterol trifenatate 25 microgram/actuation, inhalation: powder for, 30 actuations and fluticasone furoate 200 microgram/actuation + vilanterol trifenatate 25 microgram/actuation, inhalation: powder for, 30 actuations Breo® Ellipta® GlaxoSmithKline Australia Pty Ltd	Asthma	To request a Restricted Benefit General Schedule listing for the treatment of patients with frequent episodes of asthma who are 12 years or older and who are undergoing treatment with an optimal dose of an inhaled corticosteroid or who are undergoing treatment with a combination of an inhaled corticosteroid and a long-acting beta-2-agonist.
Re-submission (Major submission)	FOLLITROPIN ALFA AND LUTOPIN ALFA, follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance dilent [1 vial], 1 pack Pergoveris® Merck Serono Australia Pty Ltd	Assisted reproductive therapies	A resubmission to request a PBS listing on the Section 100 IVF/GIFT Program for the treatment of patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule and who have severe LH deficiency.
Change to Listing (Minor submission)	FOLLITROPIN BETA, 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge, 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge and 900 international units/1.108 mL injection, 1 x 1.08 mL cartridge Puregon® Merck Sharp and Dohme (Australia) Pty Ltd	Assisted reproductive therapies	To request that the PBAC confirm that follitropin alfa is not bioequivalent with follitropin beta and to request the Department advise the Department of Human Services on the changes that would be required for their claim forms.
New Listing (Minor submission)	GLUCOSE INDICATOR BLOOD, glucose indicator blood strip: diagnostic, 25 diagnostic strips, 50 diagnostic strips and 100 diagnostic strips Easy Mate II Blood Glucose Meter Strips Wincot Pty Ltd	Diabetes	To request the listing of a new brand of blood glucose test strips.

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New Listing (Minor submission)	HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELELMENTS AND LOW IN PROTEIN AND CARBOHYDRATE, oral liquid, 32 x 200 mL tetrapak KETOCAL® 4:1 LQ Nutricia Australia Pty Ltd	Medicinal food	To request a General Schedule restricted benefit listing for patients requiring a ketogenic diet, for the treatment intractable childhood epilepsy, glucose transporter protein (GLUT-1) deficiency and pyruvate dehydrogenase deficiency (PDHD).
New Listing (Major submission)	INDACATEROL AND GLYCOPYRRONIUM (FDC), indacaterol 110 microgram + glycopyrronium 50 microgram inhalation: powder for, 30 capsules Ultibro Breezhaler 110/50® Novartis Pharmaceuticals Australia Pty Ltd	Chronic Obstructive Pulmonary Disease (COPD)	To request Restricted Benefit General Schedule listing for once daily maintenance bronchodilation in patients with chronic obstructive pulmonary disease (COPD) currently on LABA or LAMA monotherapy and requiring further relief from symptoms.
Change to Listing (Major submission)	INFLIXIMAB, 100 mg injection, 1 x 100 mg vial Remicade® Janssen-Cilag Pty Ltd	Ulcerative Colitis	To request Section 100 Highly Specialised Drugs Program (HSD) listing for the treatment of moderate to severe ulcerative colitis in patients who have failed to respond to conventional therapy and meet certain criteria.
Change to Listing (Minor submission)	INTERFERON BETA-1A, 30 microgram (6 million international units) injection [4 x 30 microgram vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack and 30 microgram/0.5 mL (6 million international units) injection, 4 x 0.5 mL syringes Avonex® Biogen Idec Australia Pty Ltd	Multiple sclerosis	To request that the current Authority Required listing for interferon beta-1a be changed to Authority Required (STREAMLINED).
Re-submission (Major submission)	IVACAFTOR, 150 mg tablet, 56 Kalydeco® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic Fibrosis	Re-submission to request Section 100 Highly Specialised Drugs (HSD) listing with or without Rule of Rescue consideration or LSDP listing for the treatment of cystic fibrosis in patients 6 years and older who have confirmed class III (gating) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

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Change to Listing (Major submission)	IVERMECTIN, 3 mg tablet, 4 Stromectol® Merck Sharp & Dohme (Australia) Pty Ltd	Scabies	To request Authority Required (STREAMLINED) General Schedule listing for the treatment of scabies where prior topical treatment has failed or is contra-indicated and for crusted scabies in conjunction with topical therapy.
Change to Listing (Minor submission)	LENALIDOMIDE, 5 mg capsule, 21, 10 mg capsule, 21, 15 mg capsule, 21 and 25 mg capsule, 21 Revlimid® Celgene Pty Ltd	Multiple myeloma	To request changes to the existing Section 100 (Highly Specialised Drugs Program) restrictions to require prior treatment failure with thalidomide or bortezomib in patients with multiple myeloma.
Re-submission (Minor submission)	LEVONORGESTREL, 13.5 mg drug delivery system: intrauterine, 1 system Jaydess® Bayer Australia Limited	Contraception	Resubmission to request the PBS listing of levonorgestrel as an ultralow dose contraceptive system.
New Listing (Major submission)	LURASIDONE HYDROCHLORIDE, 40 mg tablet, 30 and 80 mg tablet, 30 Latuda® Dainippon Sumitomo Pharma Ltd	Schizophrenia	To request Authority Required (STREAMLINED) General Schedule listing for the treatment of schizophrenia.
New Listing (Major submission)	MACITENTAN, 10 mg tablet, 30 Opsumit® Actelion Pharmaceuticals Australia Pty Ltd	Pulmonary Arterial Hypertension (PAH)	To request a Section 100 Highly Specialised Drugs (HSD) Program Authority Required listing for the treatment of idiopathic pulmonary arterial hypertension (PAH) and PAH associated with connective tissue disease and PAH associated with congenital heart disease, in patients with World Health Organisation Functional Classification III and IV who meet certain criteria.

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New Listing (Minor submission)	MACROGOL 3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE macrogol 3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.66 mmol potassium) + sodium bicarbonate 178.5 mg solution, 500 mL Movicol® Liquid Norgine Pty Limited	Constipation	To request General Schedule restricted benefit and palliative care schedule listing and quadriplegic association program for the treatment of constipation.
Change to Listing (Minor submission)	NATALIZUMAB, 300 mg/15 mL injection, 1 x 15 mL vial Tysabri® Biogen Idec Australia Pty Ltd	Multiple sclerosis	To request that the current Authority Required listing for natalizumab be changed to Authority Required (STREAMLINED).
New Listing (Minor submission)	OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE, oestradiol 1 mg tablet [14 tablets] (&) oestradiol 1 mg + dydrogesterone 10 mg tablet [14 tablets], 28 Femoston 1/10® Abbott Australasia Pty Ltd	Hormone Replacement Therapy (HRT)	To request a General Schedule unrestricted benefit for the treatment of menopause related symptoms.
Re-submission (Minor submission)	OESTRADIOL + DYDROGESTERONE, oestradiol 1 mg + dydrogesterone 5 mg tablet, 28 Femoston Conti® Abbott Australasia Pty Ltd	Hormone Replacement Therapy (HRT)	Resubmission to request a General Schedule unrestricted benefit for the treatment of menopause related symptoms.
New Listing (Minor submission)	OESTRADIOL, 10 microgram pessary: modified release,18 Vagifem Low ® Novo Nordisk Pharmaceuticals Pty Ltd	Atrophic vaginitis	To request a General Schedule unrestricted benefit listing for the treatment of atrophic vaginitis due to oestrogen deficiency.

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New Listing (Minor submission)	OMALIZUMAB, 75 mg/0.5 mL injection, 1 x 0.5 mL syringe and 150 mg/1 mL injection, 1 x 1mL syringe Xolair® Novartis Pharmaceuticals Australia Pty Ltd	Severe allergic asthma	To request listing as a Section 100 (Highly Specialised Drugs Program) +/- STREAMLINED benefit, a new presentation of omalizumab, for the existing indication of uncontrolled severe allergic asthma.
Change to Listing (Major submission)	PACLITAXEL-NANOPARTICLE ALBUMIN BOUND, 100 mg injection, 1 x 100 mg Abraxane® Specialised Therapeutics Australia Pty Ltd	Pancreatic cancer	To request Section 100 [Efficient Funding of Chemotherapy (Public and Private)] Authority Required (STREAMLINED) listing for the treatment, in combination with gemcitabine, of patients with locally advanced, unresectable or metastatic adenocarcinoma of the pancreas.
New Listing (Major submission)	PERTUZUMAB, 420 mg/14 mL injection, 1 x 14 mL vial Perjeta® Roche Products Pty Limited	Breast Cancer	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required listing of pertuzumab for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2 positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
New Listing (Major submission)	PROGESTERONE, 100 mg pessary, 21 Endometrin® Ferring Pharmaceuticals Pty Ltd	Assisted reproductive therapies	To request a PBS listing as part of Section 100 IVF/GIFT Program for luteal phase support in patients who are receiving medical treatment as described in items 13200 or 13201 in the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive β-hCG measurement.
New Listing (Minor submission)	RANIBIZUMAB, 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe Lucentis® Novartis Pharmaceuticals Australia Pty Ltd	Neovascular age-related macular degeneration	To request a General Schedule Authority Required listing for a new presentation of ranibizumab for the treatment of neovascular age-related macular degeneration.

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Re-submission (Minor submission)	RANIBIZUMAB, 2.3 mg/0.23 mL, 1 x 0.23 mL vial Lucentis® Novartis Pharmaceuticals Australia Pty Ltd	Visual impairment due to diabetic macular oedema and macular oedema secondary to retinal vein occlusion.	Resubmission addressing concerns raised by the PBAC at its November 2013 meeting for the treatment of visual impairment due to diabetic macular oedema (DME) and macular oedema secondary to retinal vein occlusion (RVO).
New Listing (Major submission)	RIOCIGUAT, 500 microgram tablet, 42 and 84, 1 mg tablet, 42 and 84, 1.5 mg tablet, 42 and 84 and 2 mg tablet, 42 and 84 Adempas® Bayer Australia Ltd	Pulmonary Arterial Hypertension (PAH)	To request Section 100 Highly Specialised Drugs (HSD) program Authority Required listing for the treatment of pulmonary arterial hypertension (PAH) in patients who meet certain criteria.
New Listing (Minor submission)	SOMATROPIN, 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge Omnitrope® Sandoz Pty Ltd	Human Growth Hormone deficiencies	To request listing of an additional brand of somatropin 45 international units on the Section 100 (Human Growth Hormone Program).
New Listing (Major submission)	TRAMETINIB, 500 microgram tablet, 30, 1 mg tablet, 30 and 2 mg tablet, 30 Mekinist® GlaxoSmithKline Australia Pty Ltd	Melanoma	To request Authority Required General Schedule listing of trametinib for use, in combination with dabrafenib,j for the treatment of patients with BRAF V600 mutation positive unresectable stage III or metastatic (stage IV) melanoma.
Re-submission (Major submission)	TRASTUZUMAB EMTANSINE, 100 mg injection, 1 x 100 mg vial and 160 mg injection, 1 x 160 mg vial Kadcyla® Roche Products Pty Limited	Breast Cancer	The resubmission requests a Section 100 (Efficient Funding of Chemotherapy Drugs program) Authority Required listing for the treatment of patients with HER2 positive metastatic breast cancer (stage IV) who have received prior therapy with trastuzumab and a taxane who meet certain criteria.

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New Listing (Major submission)	UMECLIDINIUM BROMIDE AND VILANTEROL TRIFENATATE, umeclidinium bromide 62.5 microgram/actuation + vilanterol trifenatate 25 microgram/actuation inhalation: powder for, 30 actuations and umeclidinium bromide 125 microgram/actuation + vilanterol trifenatate 25 microgram/actuation inhalation: powder for, 30 actuations Anoro™ Ellipta® GlaxoSmithKline Australia Pty Ltd	Chronic Obstructive Pulmonary Disease (COPD)	To request a Restricted Benefit listing for the treatment of adult patients with chronic obstructive pulmonary disease (COPD) where symptoms persist despite regular bronchodilator treatment with a long acting muscarinic agonist (LAMA) and/or long acting beta$_2$-agonist (LABA); or for the treatment of adult patients who have been stabilised on a combination of a LAMA and a LABA in separate devices.
Re-submission (Major submission)	VARENICLINE, 500 microgram tablet [11 tablets] (&) 1mg tablet [42 tablets], 53 and 1 mg tablet, 56 Champix® Pfizer Australia Pty Ltd	Smoking cessation	Re-submission to change the NOTE to the restriction to permit a further course of varenicline tartrate in patients who did not cease smoking after a 12 week course of treatment, provided 6 months have elapsed between varenicline treatments.
Change to Listing (Major submission)	VORICONAZOLE, 50 mg tablet, 56, 200 mg tablet, 56 and 40 mg/mL oral liquid: powder for, 70 mL Vfend® Pfizer Australia Pty Ltd	Fungal Infection	To request an Authority Required listing for prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections.
Re-submission (Major submission)	ZOSTER VIRUS VACCINE LIVE, 0.65 mL injection, prefilled syringe Zostavax® bioCSL (Australia) Pty Ltd	Herpes zoster (shingles)	Resubmission to reinstate the PBAC recommendation for the listing of zoster virus vaccine live (Zostavax) on the National Immunisation Program (NIP) for the vaccination of an ongoing cohort of 60 year olds and a catch-up cohort of 61 to 79 year olds.