

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

Closing date for consumer comments 10 June 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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New listing (Major Submission)	<p>ACLIDINIUM BROMIDE with EFORMOTEROL FUMARATE DIHYDRATE</p> <p>aclidinium 340 microgram/actuation + eformoterol 12 microgram/actuation inhalation: powder for, 60 actuations</p> <p>BRIMICA® GENUAIR®</p> <p>A.Menarini Australia Pty Ltd</p>	Chronic obstructive pulmonary disease	Authority Required (STREAMLINED) listing for the treatment of patients with chronic obstructive pulmonary disease.
Change to listing (Major Submission)	<p>ADALIMUMAB</p> <p>40 mg/0.8 mL injection, 2 x 0.8 mL cartridges 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges 40 mg/0.8 mL injection, 6 x 0.8 mL syringes</p> <p>HUMIRA®</p> <p>AbbVie Pty Ltd</p>	Ulcerative colitis	Re-submission for Authority Required listing for the treatment of patients with moderate to severe ulcerative colitis.
New listing (Major Submission)	<p>AFATINIB DIMALEATE</p> <p>20 mg tablet, 28 50 mg tablet, 28 40 mg tablet, 28 30 mg tablet, 28</p> <p>GIOTRIF®</p> <p>Boehringer Ingelheim Pty Limited</p>	Non-small cell lung cancer	Re-submission for Authority Required listing for the treatment of patients with stage IIIB (locally advanced) or stage IV (metastatic) non-small cell lung cancer with epidermal growth factor receptor mutation(s).

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New listing (Minor Submission)	BENDAMUSTINE powder for injection 100 mg vial, 1 powder for injection 25 mg vial, 1 RIBOMUSTIN® Janssen Cilag Pty Ltd	Non-Hodgkin's lymphoma	Re-submission for Section 100 (Efficient Funding of Chemotherapy arrangements) listing for the first line treatment of indolent non-Hodgkin's lymphoma and mantle cell lymphoma.
Change to listing (Minor Submission)	BOSENTAN; EPOPROSTENOL; MACITENTAN bosentan 62.5 mg tablet, 60; bosentan 125 mg tablet, 60; epoprostenol 500 microgram injection vial, 1; epoprostenol 1.5 mg injection vial, 1; macitentan 10 mg tablet, 30 TRACLEER®; VELETR®; OPSUMIT® Actelion Pharmaceuticals Australia Pty Ltd	Pulmonary Arterial Hypertension	Removal of the following requirements from the 'Continuing treatment' restriction: (i) patient must have been assessed as having achieved a response to their most recent course of treatment; and (ii) clinicians must provide evidence that a patient has been assessed as having achieved response when wanting to prescribe continued treatment.

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New listing (Major Submission)	BRINZOLAMIDE with BRIMONIDINE TARTRATE suspension containing brinzolamide 10 mg/mL + brimonidine 2 mg/mL, 5 mL SIMBRINZA® Alcon Laboratories Australia Pty Ltd	Elevated intra-ocular pressure	Restricted Benefit listing for the treatment of elevated ocular pressure in adult patients with open-angle glaucoma or ocular hypertension.
New listing (Major Submission)	CARGLUMIC ACID 200 mg dispersible tablet, 5 200 mg dispersible tablet, 60 CARBAGLU® Emerge Health	Hyperammonaemia	Authority Required listing for the treatment of hyperammonaemia due to organic acidaemias including isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia.

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Change to listing (Minor Submission)	DAPAGLIFLOZIN and METFORMIN XR dapagliflozin 10 mg + metformin hydrochloride 500 mg tablet: modified release, 28 dapagliflozin 10 mg + metformin hydrochloride 1000 mg tablet: modified release, 28 dapagliflozin 5 mg + metformin hydrochloride 1000 mg tablet: modified release, 56 XIGDUO® XR AstraZeneca Pty Ltd	Type 2 diabetes mellitus	Authority Required (STREAMLINED) listing for triple oral therapy and add-on to insulin therapy in the management of type 2 diabetes mellitus.
Change to recommended listing (Major Submission)	DEFERASIROX 125 mg dispersible tablet, 28 250 mg dispersible tablet, 28 500 mg dispersible tablet, 28 EXJADE® Novartis Pharmaceuticals Australia Pty Limited	Chronic iron overload	Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of chronic iron overload.

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New listing (Major Submission)	ELIGLUSTAT eliglustat tartrate 100 mg hard capsule (equivalent to 84 mg eliglustat), 56 CERDELGA® Sanofi-aventis (Genzyme)	Gaucher Disease	Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of Gaucher Disease Type 1.
Change to recommended listing (Major Submission)	EXENATIDE 2 mg, powder for injection, vial BYDUREON® AstraZeneca Australasia Pty Ltd	Type 2 diabetes mellitus	Re-submission for Authority Required (STREAMLINED) listing for the treatment of Type 2 diabetes as: 1) Dual combination therapy with metformin or a sulfonylurea; and 2) Triple combination therapy with metformin and a sulfonylurea; in a patient who meets certain criteria.

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New listing (Major Submission)	FENTANYL CITRATE (BUCCAL) 100 microgram tablet: buccal, 4 100 microgram tablet: buccal, 28 200 microgram tablet: buccal, 4 200 microgram tablet: buccal, 28 400 microgram tablet: buccal, 4 400 microgram tablet: buccal, 28 600 microgram tablet: buccal, 4 600 microgram tablet: buccal, 28 800 microgram tablet: buccal, 4 800 microgram tablet: buccal, 28 FENTORA® Orphan Australia Pty Ltd	Breakthrough pain	Authority Required (Palliative Care Schedule) listing for the treatment of breakthrough cancer pain.

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New listing (Major Submission)	FENTANYL CITRATE (SUBLINGUAL) 100 microgram tablet: sublingual, 10 100 microgram tablet: sublingual, 30 200 microgram tablet: sublingual, 10 200 microgram tablet: sublingual, 30 300 microgram tablet: sublingual, 10 300 microgram tablet: sublingual, 30 400 microgram tablet: sublingual, 10 400 microgram tablet: sublingual, 30 600 microgram tablet: sublingual, 10 600 microgram tablet: sublingual, 30 800 microgram tablet: sublingual, 10 800 microgram tablet: sublingual, 30 ABSTRAL® A.Menarini Australia Pty Ltd	Breakthrough pain	Re-submission for Authority Required (Palliative Care Schedule) listing for the treatment of breakthrough cancer pain.
New listing (Minor Submission)	GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS with VITAMINS and MINERALS 15 g protein oral liquid, 30 x 250 mL tetra pack TYLACTIN® RTD Cortex Health Pty Ltd	Medicinal food	Restricted Benefit listing of an alternative medicinal food for patients with tyrosinaemia.

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New listing (Major Submission)	IBRUTINIB 140 mg capsules, 90 IMBRUVICA® Janssen Cilag Pty Ltd	Chronic lymphocytic leukaemia	Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory chronic lymphocytic leukaemia and relapsed or refractory small lymphocytic lymphoma.
New listing (Minor Submission)	INFLIXIMAB 100 mg injection vial, 1 100 mg injection vial, 3 100 mg injection vial, 4 INFLECTRA® Hospira Pty Ltd	Ankylosing spondylitis Crohn's disease Psoriatic arthritis Rheumatoid Arthritis Plaque psoriasis Ulcerative colitis	Section 100 (Highly Specialised Drugs Program) Authority Required listing of Inflectra (infliximab), a similar biological medicinal product, with the same indications and restrictions as the currently PBS listed brand of infliximab (Remicade®).
New listing (Major Submission)	INSULIN GLARGINE 300 unit/mL, 1 x 1.5 mL cartridge 300 unit/mL, 3 x 1.5 mL cartridge 300 unit/mL, 5 x 1.5 mL cartridge TOUJEO® Sanofi-aventis	Diabetes	Unrestricted benefit listing.

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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 further advice from the PBAC regarding its previous recommendation for the PBS listing of Basaglar.
Change to listing (Minor Submission)	IVACAFTOR 150 mg tablet, 56 KALYDECO® Vertex Pharmaceuticals Pty Ltd	Cystic fibrosis	Amendment to the PBS restriction to enable a higher dose of ivacaftor in patients who are concomitantly on a strong CYP3A4 inhibitor.
Change to listing (Minor Submission)	LEUPRORELIN 30 mg injection: modified release [1 x 30 mg syringe] (& inert substance diluent [1 x 2 mL syringe], 1 LUCRIN® DEPOT AbbVie Pty Ltd	Central precocious puberty	Amendment to the PBS restriction wording of Lucrin® Depot Paediatric to specify that the patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).

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New listing (Minor Submission)	LEUPRORELIN 45 mg injection: modified release [1 x 45 mg syringe] (& inert substance diluent [1 x 2 mL syringe], 1 LUCRIN® DEPOT 6 month PDS AbbVie Pty Ltd	Prostate cancer	Authority Required (STREAMLINED) listing of an additional strength of leuprorelin for the treatment of locally advanced or metastatic carcinoma of the prostate.
Change to listing (Minor Submission)	MANNITOL powder for inhalation, 40 mg capsules, 280 BRONCHITOL® Pharmaxis Ltd	Cystic fibrosis	Amendment of the PBS restriction to consolidate the wording and to enable use in combination with dornase alfa.
Change to listing (Minor Submission)	MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE (4CMENB) 0.5 mL suspension for injection pre-filled syringe BEXSERO® Novartis Vaccines and Diagnostics Pty Ltd (an affiliate of GlaxoSmithKline LLC)	Meningococcal B disease	Re-submission for inclusion on the National Immunisation program for the prevention of meningococcal B disease in infants and adolescents.

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New listing (Major Submission)	<p>NADROPARIN CALCIUM</p> <p>1900 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL pre-filled syringe 2850 anti-Xa international units/0.3 mL injection, 10 x 0.3 mL pre-filled syringe 3800 anti-Xa international units/0.4 mL injection, 10 x 0.4 mL pre-filled syringe 5700 anti-Xa international units/0.6 mL injection, 10 x 0.6 mL pre-filled syringe 7600 anti-Xa international units/0.8 mL injection, 10 x 0.8 mL pre-filled syringe 9500 anti-Xa international units/1 mL injection, 10 x 1 mL pre-filled syringe 11400 anti-Xa international units/0.6 mL injection, 10 x 0.6 mL pre-filled syringe 15200 anti-Xa international units/0.8 mL injection, 10 x 0.8 mL pre-filled syringe 19000 anti-Xa international units/1 mL injection, 10 x 1 mL pre-filled syringe</p> <p>FRAXIPARINE® FRAXIPARINE FORTE®</p> <p>Aspen Pharmacare Australia Pty Ltd</p>	Prevention of deep vein thrombosis	Unrestricted benefit listing and restricted benefit listing for prevention of clotting during haemodialysis.

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New listing (Minor Submission)	NETUPITANT and PALONOSETRON netupitant 300 mg + palonosetron 0.5 mg, 1 AKYNZERO® Specialised Therapeutics Australia Pty Ltd	Nausea and vomiting	Re-submission for section 100 (Efficient Funding of Chemotherapy - Related Benefits) and General Schedule listing for the prevention of nausea and vomiting in patients receiving highly emetogenic chemotherapy and for breast cancer patients receiving an anthracycline-based chemotherapy regimen.
New listing (Minor Submission)	NITISINONE 2 mg capsule, 60 5 mg capsule, 60 10 mg capsule, 60 ORFADIN® A. Menarini Australia Pty Ltd	Tyrosinaemia	Re-submission for section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of hereditary tyrosinaemia type 1.
New listing (Major Submission)	NIVOLUMAB concentrate solution for infusion, 10 mg/mL, 1 x 4ml vial concentrate solution for infusion, 10 mg/mL, 1 x 10ml vial OPDIVO® Bristol-Myers Squibb Australia Pty Ltd	Melanoma	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable stage III or stage IV malignant melanoma.

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New listing (Major Submission)	PARITAPREVIR with RITONAVIR, OMBITASVIR and DASABUVIR PARITAPREVIR with RITONAVIR, OMBITASVIR, DASABUVIR and RIBAVIRIN paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet, 56, with dasabuvir 250 mg tablet, 56 paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet, 56, with dasabuvir 250 mg tablet, 56 and ribavirin 200 mg tablet, 168 paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet, 56, with dasabuvir 250 mg tablet, 56, and ribavirin 600 mg tablet, 56 VIEKIRA PAK VIEKIRA PAK-RBV AbbVie Pty Ltd	Hepatitis C	Authority Required (STREAMLINED) listing for the treatment of patients with genotype 1 chronic hepatitis C.
New listing (Major Submission)	PERTUSSIS VACCINE-ACELLULAR, combined with DIPHTHERIA and TETANUS TOXOIDS (DTaP) 0.5 ml vial, 1 TRIPACEL® Sanofi-aventis Australia Pty Ltd	Prevention of diphtheria, tetanus and pertussis	National Immunisation Program listing of an additional booster dose of DTaP vaccine for children aged 18 months.

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Change to listing (Minor Submission)	PNEUMOCOCCAL CONJUGATE VACCINE (13-valent) 0.5 mL injection PREVENAR 13® Pfizer Australia Pty Ltd	Pneumococcal disease	Re-submission to extend the listing on the National Immunisation Program to include the prevention of pneumococcal disease in non-Indigenous adults aged 65 years and Indigenous adults aged 50 years.
New listing (Major Submission)	PONATINIB 15 mg tablet, 60 45 mg tablet, 30 ICLUSIG® Specialised Therapeutics Australia Pty Ltd	Chronic myeloid leukaemia and acute lymphoblastic leukaemia	Re-submission for Authority Required listing for the treatment of chronic myeloid leukaemia or acute lymphoblastic leukaemia in a patient who meets certain criteria.
New listing (Major Submission)	QUADRIVALENT INFLUENZA VACCINE 0.5 ml pre-filled syringe, 5 0.5 ml pre-filled syringe, 10 0.25 ml pre-filled syringe, 5 0.25 ml pre-filled syringe, 10 FLUQUADRI® Sanofi-aventis	Prevention of seasonal influenza	National Immunisation Program listing for the prevention of seasonal influenza in the currently eligible patient populations.

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Change to listing (Minor Submission)	RIBAVIRIN 400 mg tablet, 28 600 mg tablet, 28 IBAVYR® Clinect Py Ltd	Hepatitis C	Re-submission for section 85 Authority Required (STREAMLINED) listing for the treatment of hepatitis C viral infection in patients 18 years or older who have compensated liver disease.
New listing (Major Submission)	RIOCIQUAT 0.5 mg tablet, 42 0.5 mg tablet, 84 1 mg tablet, 42 1 mg tablet, 84 1.5 mg tablet, 42 1.5 mg tablet, 84 2 mg tablet, 42 2 mg tablet, 84 2.5 mg tablet, 42 2.5 mg tablet, 84 ADEMPAS® Bayer Australia Limited	Chronic thromboembolic pulmonary hypertension	Re-submission for section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with chronic thromboembolic pulmonary hypertension.

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Change to listing (Minor Submission)	RIVASTIGMINE 13.3 mg/24 hours patch, 30 EXELON® Novartis Pharmaceuticals Australia Pty Limited	Dementia	Authority Required listing of an additional strength for the treatment of mild to moderately severe Alzheimer-type dementia.
Change to listing (Minor Submission)	SAXAGLIPTIN and METFORMIN XR saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28 saxagliptin 5 mg + metformin hydrochloride 1000 mg tablet: modified release, 28 saxagliptin 2.5 mg + metformin hydrochloride 1000 mg tablet: modified release, 56 KOMBIGLYZE® XR AstraZeneca Pty Ltd	Type 2 diabetes mellitus	Authority Required (STREAMLINED) listing for triple oral therapy in the management of type 2 diabetes mellitus.
Change to listing (Major Submission)	SAXAGLIPTIN 2.5 mg tablet, 28 5.0 mg tablet, 28 ONGLYZA® AstraZeneca Pty Ltd	Type 2 diabetes mellitus	Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus.

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Change to recommended listing (Major Submission)	SIMEPREVIR 150mg capsule, 7 OLYSIO® Janssen Cilag Pty Ltd	Hepatitis C	Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with genotype 1 chronic hepatitis C.

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Change to listing (Major Submission)	SITAGLIPTIN SITAGLIPTIN and METFORMIN SITAGLIPTIN and METFORMIN XR sitagliptin 100 mg tablet, 28 sitagliptin 50 mg tablet, 28 sitagliptin 25 mg tablet, 28 sitagliptin 50 mg + metformin hydrochloride 1000 mg tablet, 56 sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 sitagliptin 100 mg + metformin hydrochloride 1000 mg tablet: modified release, 28 sitagliptin 50 mg + metformin hydrochloride 1000 mg tablet: modified release, 56 JANUVIA® JANUMET® JANUMET XR® Merck Sharp & Dohme (Australia) Pty Limited	Type 2 diabetes mellitus (in combination with insulin)	Authority Required (STREAMLINED) listing for use in combination with insulin in patients with type 2 diabetes mellitus.

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Change to listing (Major Submission)	SITAGLIPTIN SITAGLIPTIN and METFORMIN SITAGLIPTIN and METFORMIN XR sitagliptin 100 mg tablet, 28 sitagliptin 50 mg tablet, 28 sitagliptin 25 mg tablet, 28 sitagliptin 50 mg + metformin hydrochloride 1000 mg tablet, 56 sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 sitagliptin 100 mg + metformin hydrochloride 1000 mg tablet: modified release, 28 sitagliptin 50 mg + metformin hydrochloride 1000 mg tablet: modified release, 56 JANUVIA® JANUMET® JANUMET XR® Merck Sharp & Dohme (Australia) Pty Limited	Type 2 diabetes mellitus (triple oral therapy)	Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus.

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

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Change to listing (Minor Submission) WITHDRAWN	SORAFENIB 200 mg tablet Nevaxar® Bayer Australia Limited	Thyroid cancer	Re-submission for Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic, radioactive iodine refractory differentiated thyroid cancer.
Change to recommended listing (Major Submission)	STRONTIUM RANELATE 2 g granules for oral suspension, 28 x 2g sachets PROTOS® Servier Laboratories	Osteoporosis	To not delist the current Authority Required listing for the treatment of severe established osteoporosis.
Change to listing (Minor Submission)	TESTOSTERONE testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations testosterone 2.5 mg/24 hours patch, 60 testosterone 5 mg/24 hours patch, 30 Various sponsors National Lesbian, Gay, Bisexual, Transgender, and Intersex Health Alliance	Androgen deficiency	Amendment to the revised PBS restrictions to enable access by transgender and intersex patients.

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New listing (Major Submission)	<p>TIOTROPIUM BROMIDE with OLODATEROL HYDROCHLORIDE</p> <p>tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation: solution for, 60 actuations</p> <p>SPIOLTO® RESPIMAT®</p> <p>Boehringer Ingelheim Pty Limited</p>	Chronic obstructive pulmonary disease	Authority Required (STREAMLINED) listing for the treatment of patients with chronic obstructive pulmonary disease.
Change to recommended listing (Major Submission)	<p>TIOTROPIUM BROMIDE</p> <p>tiotropium 2.5 microgram inhalation: solution for, 60 actuations</p> <p>SPIRIVA® RESPIMAT®</p> <p>Boehringer Ingelheim Pty Limited</p>	Asthma	Restricted Benefit listing for the treatment of severe asthma.
Matters Outstanding (Major Submission)	<p>TRASTUZUMAB</p> <p>powder for I.V. infusion, 60 mg vial, 1 powder for I.V. infusion, 150 mg vial, 1</p> <p>HERCEPTIN®</p> <p>Roche Products Pty Ltd</p>	Gastric cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with HER2 positive, metastatic (equivalent to stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction.

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New listing (Minor Submission)	TRASTUZUMAB solution for subcutaneous injection, 600 mg/5 mL, 1 HERCEPTIN® Roche Products Pty Ltd	Breast cancer	Authority Required listing of a subcutaneously administered formulation for the treatment of HER2 positive breast cancer.
Change to listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN FORMULA oral liquid: powder for, 400 g PEPTAMEN JUNIOR® Nestle Health Science (Nestle Australia Ltd)	Medicinal food	Amendment to the current PBS restriction 'NOTE' to allow an increase in the maximum quantity.
Change to listing (Minor Submission)	USTEKINUMAB 45 mg/0.5 mL injection vial, 1 STELARA® Janssen Cilag Pty Ltd	Psoriatic arthritis	Re-submission for Authority Required listing for the treatment of severe active psoriatic arthritis.

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Post-market review report (Review of Authority Required PBS Listings)	Authority Required medicines in Tranche 3 (ocular lubricants, specialised medical foods and palliative care medicines), opioids and antibiotics. Refer to the Review website for the full list of medicines included in the Review.	Various	To review the Authority Required restrictions on these medicines, with the aim of reducing regulatory burden on prescribers, pharmacists and patients.
Sub-committee report (DUSC Analysis)	Atomoxetine (Strattera®), Dexamphetamine (Aspen®, Methylphenidate (Ritalin 10®, Ritalin LA®, Concerta®)	Attention Deficient Hyperactivity Disorder	To review the utilisation of PBS-listed medicines used in the management of attention deficit hyperactivity disorder.
Sub-committee report (DUSC Analysis)	Aflibercept (Eylea®) Ranibizumab (Lucentis®), Verteporfin (Visudyne®)	Age-related Macular Degeneration	To assess the utilisation of PBS listed medicines for age related macular degeneration, including a 24 month predicted versus actual analysis of aflibercept (listed 1 December 2012).
Sub-committee report (DUSC Analysis)	Dutasteride(Avodart®), Dutasteride with tamsulosin (Duodart®)	Lower urinary tract symptoms due to benign prostatic hyperplasia	To compare the predicted and actual utilisation of dutasteride, and dutasteride with tamsulosin fixed dose combination product since they were listed on the PBS in February 2011 and August 2011 respectively.
Sub-committee report (DUSC Analysis)	Icatibant (Firazyr®)	Hereditary angioedema	To compare the predicted and actual utilisation of icatibant during the first 24 months of PBS listing (1 August 2012 to 31 July 2014).

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Sub-committee report (DUSC Analysis)	Romiplostim (NPlate®), Eltrombopag (Revolade®)	Idiopathic thrombocytopenic purpura	To examine the utilisation of the thrombopoietin receptor agonists, romiplostim and eltrombopag, for idiopathic thrombocytopenic purpura since their listings on the PBS from April 2011 and November 2011, respectively.