

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 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.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<b>Submission type</b> <i>(new drug application, changes to listings, resubmissions)</i>	<b>Drug Name, form(s), strength(s) and Sponsor</b> <i>(Drug name, form, strength, Trade name<sup>®</sup>, Sponsor)</i>	<b>Drug Type and Use</b> <i>(What is the drug used to treat?)</i>	<b>Listing requested by Sponsor / Purpose of Submission</b> <i>(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased)</i>
Change to Listing (Major submission)	ABIRATERONE abiraterone acetate 250 mg tablet  Zytiga <sup>®</sup>  Janssen-Cilag Pty Ltd	Prostate cancer	To request extension of the current Section 85 Authority required listing for abiraterone for the treatment of metastatic castration resistant prostate cancer (mCRPC) to include patients who have progressed following treatment with androgen deprivation therapy (ADT), who would not have benefit from immediate chemotherapy.
Re-submission (Major submission)	ADALIMUMAB adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges and 2 x 0.8 mL syringes  adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges and 6 x 0.8 mL syringes  Humira <sup>®</sup>	Ulcerative colitis	The resubmission requests a Section 85 Authority required listing for the treatment of moderately to severely active ulcerative colitis
New Listing (Major submission)	ALEMTUZUMAB alemtuzumab 10 mg/mL injection, 1 x 2 mL vial  Lemtrada <sup>®</sup>  Genzyme (A Sanofi company)	Multiple sclerosis	To request Section 100 (Highly Specialised Drugs Program) Authority required listing for the treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory patients aged 18 year or older who meet certain criteria.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>Change to Listing (Minor submission)</p>	<p>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE amino acid formula with vitamins and minerals without phenylalanine oral liquid</p> <p>PKU Lophlex LQ 10® &amp; PKU Lophlex LQ 20®</p> <p>Nutricia Australia Pty Ltd</p>	<p>Medicinal food</p>	<p>To inform the Nutritional Products Working Party and the PBAC of additional flavour variants and minor nutritional upgrades within the currently listed PKU Lophlex LQ 10 and 20 range for treatment of patients with phenylketonuria (PKU).</p> <p>No changes to the current PBS listings are requested.</p>
<p>New Listing (Minor submission)</p>	<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 6 g sachets</p> <p>MSUD amino5®</p> <p>Vitaflo Australia Pty Ltd</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for the treatment of maple syrup urine disease (MSUD).</p>
<p>New Listing (Major submission)</p>	<p>ARIPRAZOLE aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (&amp; inert substance diluent [2 x 3 mL syringe]</p> <p>aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (&amp; inert substance diluent [2 x 3 mL syringe]</p> <p>Abilify Maintena®</p> <p>Lundbeck Australia Pty Ltd</p>	<p>Schizophrenia</p>	<p>To request an Authority required (Streamlined) listing for the treatment of schizophrenia.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

Re-submission (Minor submission)	BRENTUXIMAB VEDOTIN brentuximab vedotin, 50 mg injection, 1 x 50 mg vial  Adcetris®  Takeda Pharmaceuticals Australia Pty Ltd	Systemic anaplastic large cell lymphoma (sALCL)	To propose a re-specified economic model following the March 2014 PBAC recommendation to list brentuximab 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.  The re-submission also requests separate restrictions for initial and continuing treatment.
Re-submission (Major submission)	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM collagenase clostridium histolyticum 900 microgram injection [1 x 900 microgram vial] (&) inert substance [1 x 3 mL vial]  Xiaflex®  Actelion Pharmaceuticals Australia Pty Ltd	Dupuytren's contracture	The re-submission requests an Authority required listing for the treatment of Dupuytren's contracture in patients with two or less rays affected who are unable to simultaneously place the affected finger and palm flat on a table due to a Dupuytren's contracture with a palpable cord and who would otherwise require surgery.
Change to Listing (Minor submission)	DAPAGLIFLOZIN dapagliflozin 10 mg tablet  Forxiga®  AstraZeneca Australia Pty Ltd	Type 2 diabetes	To request amendments to the current restriction for dapagliflozin for use in diabetes mellitus type 2 to provide prescribers with clarity regarding the eligible PBS population.
New Listing (Major submission)	DAPAGLIFLOZIN + METFORMIN XR (FDC) dapagliflozin 10 mg + metformin hydrochloride 500 mg, tablet dapagliflozin 10 mg + metformin hydrochloride 1000 mg, tablet dapagliflozin 5 mg + metformin hydrochloride 1000 mg, tablet  Xigduo®XR  AstraZeneca Pty Ltd	Type 2 diabetes	To request Section 85 Authority required listing of a fixed dose combination (FDC) tablet formulation for the treatment of diabetes mellitus type 2 in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor, a thiazolidinedione or a glucagon-like peptide-1 or a sodium-glucose co-transporter, and where the condition is not able to be adequately controlled by treatment with metformin and a sulfonylurea.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>Change to Listing (Minor submission)</p>	<p>DASATINIB dasatinib 20 mg tablets dasatinib 50 mg tablets dasatinib 70 mg tablets dasatinib 100 mg tablets</p> <p>Sprycel®</p> <p>Bristol Myers Squibb Australia Pty Ltd</p>	<p>Chronic myeloid leukaemia</p>	<p>To request an amendment to the current first-line PBS restriction for dasatinib for treatment of patients with chronic myeloid leukaemia (CML) to ensure consistency with the first-line listing for the alternative tyrosine kinase inhibitor (TKI), imatinib, and to make it easier for patients to continue receiving dasatinib whilst they continue to respond to treatment in the first-line setting.</p>
<p>New Listing (Major submission)</p>	<p>EMPAGLIFLOZIN empagliflozin 10 mg tablet empagliflozin 25 mg tablet</p> <p>Jardiance®</p> <p>Boehringer Ingelheim Pty Ltd</p>	<p>Type 2 diabetes</p>	<p>To request Authority Required General Schedule listing for the treatment of diabetes mellitus type 2 as dual therapy in combination with metformin or sulfonylurea in patients with inadequate glycaemic control despite treatment with a combination of metformin and a sulfonylurea.</p>
<p>New Listing (Major submission)</p>	<p>ENZALUTAMIDE enzalutamide 40 mg capsule</p> <p>Xtandi®</p> <p>Astellas Pharma Australia Pty Ltd</p>	<p>Prostate cancer</p>	<p>To request Authority required (Streamlined) listing for the treatment of patients with metastatic castration resistant prostate cancer who have previously received docetaxel and who meet certain criteria.</p>
<p>New Listing (Minor submission)</p>	<p>EPOPROSTENOL epoprostenol 500 microgram injection, vial epoprostenol 1.5 mg injection, vial</p> <p>Veletri®</p> <p>Actelion Pharmaceuticals Australia Pty Ltd</p>	<p>Pulmonary arterial hypertension</p>	<p>To request Section 100 Highly Specialised Drugs Program listing of a new presentation of epoprostenol for the treatment of patients with pulmonary arterial hypertension (PAH).</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>New Listing (Minor submission)</p>	<p>ESCITALOPRAM escitalopram 20 mg/mL oral liquid, 15 mL</p> <p>Lexapro®</p> <p>Lundbeck Australia Pty Ltd</p>	<p>Major depressive disorders</p>	<p>To request listing of a new strength as a Restricted benefit for major depressive disorders, generalised anxiety disorders and social anxiety disorder. The submission also requests delisting the existing listed 10 mg/mL strength.</p>
<p>Change to Listing (Minor submission)</p>	<p>ETANERCEPT etanercept injection 50 mg in 1 mL single use auto-injector etanercept injection 50 mg in 1 mL single use pre-filled syringe</p> <p>Enbre®</p> <p>Pfizer Australia Pty Ltd</p>	<p>Juvenile idiopathic arthritis</p>	<p>To request PBS-listing of 50 mg presentations of etanercept for treatment of juvenile idiopathic arthritis in patients who have a body weight of 62.5 kg or greater.</p>
<p>New Listing (Major submission)</p>	<p>EZETIMIBE + ROSUVASTATIN (FDC) ezetimibe 10 mg + rosuvastatin 5 mg, tablet; ezetimibe 10 mg + rosuvastatin 10 mg, tablet; ezetimibe 10 mg + rosuvastatin 20 mg, tablet; ezetimibe 10 mg + rosuvastatin 40 mg, tablet</p> <p>Rosuzet®</p> <p>Merck Sharpe &amp; Dohme Australia Pty Ltd</p>	<p>High cholesterol</p>	<p>To request section 85 Authority required (Streamlined) listing of a fixed dose combination (FDC) tablet formulation for the treatment of hypercholesterolemia.</p>
<p>Re-submission (Minor submission)</p>	<p>FLUTICASONE FUROATE + VILANTEROL TRIFENATATE (FDC) fluticasone furoate 100 microgram/actuation + vilanterol trifenate 25 microgram/actuation, inhalation: powder for; fluticasone furoate 200 microgram/actuation + vilanterol trifenate 25 microgram/actuation, inhalation: powder for</p> <p>Breo™ Ellipta®</p> <p>GlaxoSmithKline Australia Pty Ltd</p>	<p>Chronic obstructive pulmonary disease (COPD)</p>	<p>To request a Restricted Benefit listing for the symptomatic treatment of chronic obstructive pulmonary disease (COPD), in patients where FEV1 is less than 50% of predicted normal, and where there is a history of repeated exacerbations with significant symptoms despite regular beta2-agonist bronchodilator therapy.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>New Listing (Minor submission)</p>	<p>GLUCOSE INDICATOR BLOOD glucose indicator blood strip: diagnostic</p> <p>Medissentials Diabetic Test Strips®</p> <p>S.W.R International Pty Ltd</p>	<p>Diabetes</p>	<p>To request PBS-listing of a new brand of blood glucose test strips.</p>
<p>New Listing (Minor submission)</p>	<p>GLYCINE WITH CARBOHYDRATE glycine with carbohydrate containing 500 mg L-glycine oral liquid: powder for, 30 x 4 g sachets</p> <p>Glycine500®</p> <p>Vitaflo Australia Pty Ltd</p>	<p>Medicinal food</p>	<p>To request a Restricted Benefit listing for the dietary management of isovaleric acidaemia (IVA).</p>
<p>Change to Listing (Minor submission)</p>	<p>GOLIMUMAB golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe Simponi®</p> <p>INFLIXIMAB infliximab 100 mg injection, 1 x 100 mg vial Remicade®</p> <p>USTEKINUMAB ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial Stelara®</p>	<p>Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis, Crohn disease, ulcerative colitis</p>	<p>To request a change to the second and subsequent continuing treatment authorities for golimumab, infliximab, and ustekinumab for all of their PBS-reimbursed indications from complex written authority to telephone authority items.</p> <p>The submission also requests that the Department of Human Services provide electronic PBS authority application forms for electronic completion and record keeping purposes.</p>
<p>New Listing (Major submission)</p>	<p>INCOBOTULINUMTOXIN A incobotulinumtoxinA 100 units injection, 1 x 100 units vial</p> <p>Xeomin®</p> <p>Merz Pharmaceuticals GmbH</p>	<p>Dystonia, blepharospasm post-stroke spasticity of the upper limb</p>	<p>To request Section 100 (Botulinum Toxin Program) listing for treatment of:</p> <ul style="list-style-type: none"> <li>(i) cervical dystonia (spasmodic torticollis) in adults;</li> <li>(ii) blepharospasm in adults; and</li> <li>(iii) moderate to severe spasticity of the upper limb following a stroke in adults</li> </ul>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

Re-submission (Minor submission)	INDACATEROL + GLYCOPYRRONIUM (FDC) indacaterol 110 microgram + glycopyrronium 50 microgram inhalation: powder for, 30 capsules  Ultibro Breezhaler 110/50®  Novartis Pharmaceuticals Pty Ltd	Chronic obstructive pulmonary disease.	To request a Restricted Benefit listing for once daily maintenance bronchodilation in patients with chronic obstructive pulmonary disease (COPD) currently on LABA or LAMA monotherapy and requiring additional relief from symptoms and in patients who have been stabilised on a combination of a LAMA and LABA in separate devices.
Re-submission (Minor submission)	INFLIXIMAB infliximab 100 mg powder for injection  Remicade®  Janssen-Cilag Pty Ltd	Ulcerative colitis	To propose a revised economic model following the March 2014 PBAC recommendation to extend the listing of infliximab to include treatment of moderate to severe ulcerative colitis in patients who have failed to respond to conventional therapy and who meet certain criteria.
Re-submission (Minor submission)	INGENOL ingenol mebutate gel 0.15 mg/g (0.015%), 3 x 0.47 g  Picato®  Leo Pharma Pty Ltd	Skin cancer	To request a Restricted Benefit listing for treatment, as field therapy, of solar keratoses of the face and scalp.
Re-submission (Major submission)	LISDEXAMFETAMINE lisdexamfetamine dimesilate 30 mg capsule; lisdexamfetamine dimesilate 50 mg capsule; lisdexamfetamine dimesilate 70 mg capsule;  Vyvanse®  Shire Australia Pty Ltd	Attention deficit hyperactivity disorder (ADHD)	The re-submission requests an Authority required listing for the treatment of attention deficit hyperactivity disorder (ADHD), in patients diagnosed between the ages of 6-18 years inclusive who meet certain criteria.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>New Listing (Major submission)</p>	<p>LIXISENATIDE lixisenatide 10 micrograms/0.2 mL injection, 14 unit doses (&amp; lixisenatide 20 micrograms/0.2 mL injection, 14 unit doses, pack Lyxumia® Treatment Initiation Pack</p> <p>lixisenatide 20 micrograms/0.2 mL injection, 28 unit doses Lyxumia®</p> <p>Sanofi-Aventis Australia Pty Ltd</p>	<p>Type 2 diabetes</p>	<p>To request an Authority required (Streamlined) listing for treatment of diabetes mellitus type 2 as triple combination therapy with basal insulin and either metformin or a sulphonylurea in patients who meet certain criteria.</p>
<p>New Listing (Major submission)</p>	<p>LIXISENATIDE lixisenatide 10 micrograms/0.2 mL injection, 14 unit doses (&amp; lixisenatide 20 micrograms/0.2 mL injection, 14 unit doses, pack Lyxumia® Treatment Initiation Pack</p> <p>lixisenatide 20 micrograms/0.2 mL injection, 28 unit doses Lyxumia®</p> <p>Sanofi-AventisAustralia Pty Ltd</p>	<p>Type 2 diabetes</p>	<p>To request an Authority required (Streamlined) listing for treatment of diabetes mellitus type 2 in patients who meet certain criteria as; (i) dual therapy in combination with metformin; and (ii) triple therapy in combination with metformin and a sulphonylurea.</p>
<p>New Listing (Minor submission)</p>	<p>MIFEPRISTONE &amp; MISOPROSTOL mifepristone 200 mg tablet [1 tablet] (&amp; misoprostol 200 microgram tablet [4 tablets], 1 pack</p> <p>MS-2 Step®</p> <p>MS Health Pty Ltd</p>	<p>Medical termination of an intra-uterine pregnancy</p>	<p>To request an Authority Required listing for a composite pack containing mifepristone and misoprostol for the termination of an intra-uterine pregnancy of up to 63 days gestation.</p> <p>The listing of the composite pack is intended to replace the current listings of the components, with an amended restriction consistent with revised TGA indications.</p>
<p>Re-submission (Major submission)</p>	<p>MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE (4CMENB) 0.5 mL suspension for injection pre-filled syringe</p> <p>Bexsero®</p> <p>Novartis Vaccines and Diagnostics Pty Ltd</p>	<p>Meningococcal B disease</p>	<p>Re-submission seeks inclusion on the National Immunisation program for the prevention of meningococcal B disease in infants and adolescents.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>New Listing (Major submission)</p>	<p><b>OBINUTUZUMAB</b> obinutuzumab 1000 mg/40 mL injection, 1 x 40 mL vial</p> <p>Gazyva®</p> <p>Roche Products Pty Ltd</p>	<p>Chronic lymphocytic leukaemia</p>	<p>To request Section 100 (Efficient Funding of Chemotherapy Program) Authority required listing for the treatment, in combination with chlorambucil, of patients with previously untreated CD20 positive chronic lymphocytic leukaemia (CLL) and comorbidities.</p>
<p>New Listing (Major submission)</p>	<p><b>OLODATEROL</b> olodaterol 2.5 microgram/actuation inhalation: solution for, 60 actuations</p> <p>Striverdi® Respimat®</p> <p>Boehringer Ingelheim Pty Ltd</p>	<p>Chronic obstructive pulmonary disease (COPD)</p>	<p>To request listing as a Restricted benefit for the treatment of chronic obstructive pulmonary disease (COPD).</p>
<p>Re-submission (Major submission)</p>	<p><b>PANITUMUMAB</b> panitumumab 100 mg/5 mL injection, 1 x 5 mL vial panitumumab 400 mg/20 mL injection, 1 x 20 mL vial</p> <p>Vectibix®</p> <p>Amgen Australia Pty Ltd</p>	<p>Metastatic colorectal cancer (mCRC)</p>	<p>1. Request to modify the existing later-line metastatic colorectal cancer (mCRC) panitumumab listing from eligibility based on wild type KRAS to wild type RAS.</p> <p>2. Re-submission requesting Section 100 (Efficient Funding of Chemotherapy) Authority Required (+/- Streamlined) listing for use in combination with FOLFOX as first-line chemotherapy for wild type RAS metastatic colorectal cancer.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>New Listing (Major submission)</p>	<p>PERAMPANEL perampanel 2 mg tablet perampanel 4 mg tablet perampanel 6 mg tablet perampanel 8 mg tablet perampanel 10 mg tablet perampanel 12 mg tablet</p> <p>Fycompa®</p> <p>Eisai Australia Pty Ltd</p>	<p>Epilepsy</p>	<p>To request Section 85 Authority required (Streamlined) listing for the adjunctive treatment of partial epileptic seizures.</p>
<p>New Listing (Major submission)</p>	<p>POMALIDOMIDE pomalidomide 3 mg capsules pomalidomide 4 mg capsules</p> <p>Pomalyst®</p> <p>Celgene Pty Ltd</p>	<p>Myeloma</p>	<p>To request Section 100 (Highly Specialised Drug Program) Authority required listing for treatment in combination with dexamethasone, of patients with relapsed and/or refractory multiple myeloma who have received and failed prior treatment with both lenalidomide and bortezomib.</p>
<p>Re-submission (Major submission)</p>	<p>RANIBIZUMAB ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial</p> <p>Lucentis®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p>	<p>Diabetic macular oedema (DME)</p>	<p>Re-submission seeking an Authority required listing for treatment of patients with visual impairment due to diabetic macular oedema (DME) who meet certain criteria.</p>
<p>Re-submission (Major submission)</p>	<p>RANIBIZUMAB ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial</p> <p>Lucentis®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p>	<p>Macular oedema secondary to retinal vein occlusion (RVO)</p>	<p>Re-submission seeking an Authority required listing for treatment of patients with visual impairment due to macular oedema secondary to retinal vein occlusion (RVO) who meet certain criteria.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

New Listing (Major submission)	REGORAFENIB regorafenib 40 mg tablet  Stivarga®  Bayer Australia Ltd	Metastatic colorectal cancer (mCRC)	To request an Authority required (Streamlined) listing for treatment of patients with metastatic colorectal cancer (mCRC) who have a WHO performance status of 0 or 1, following failure of or intolerance to prior therapy.
Change to listing (Minor submission)	RITUXIMAB rituximab 100 mg/10 mL injection rituximab 500 mg/50 mL injection  Mabthera®  Roche Products Pty Ltd	Non-Hodgkin's lymphoma	Re-submission to review the cost-effectiveness of rituximab for maintenance therapy of follicular lymphoma in patients who have achieved a partial or complete response to induction treatment in first-line and relapsed treatment settings.
Re-submission (Major submission)	RUXOLITINIB ruxolitinib 5 mg tablet ruxolitinib 15 mg tablet ruxolitinib 20 mg tablet  Jakavi®  Novartis Pharmaceuticals Australia Pty Ltd	Bone marrow disorder	Re-submission seeking an Authority required listing for the treatment of disease related symptoms or splenomegaly in patients with intermediate to high risk primary (idiopathic) myelofibrosis (MF), post-polycythemia MF and post-essential thrombocythemia MF who are resistant to, refractory to, intolerant of or not candidates for available therapy.
New Listing (Major submission)	SIMEPREVIR simeprevir 150 mg capsule  Olysio®  Janssen-Cilag Pty Ltd	Hepatitis C	To request Section 100 (Highly Specialised Drug Program) Private Hospital Authority required and Public Hospital Authority required (Streamlined) listing for the treatment of chronic genotype 1 hepatitis C infection in patients who meet certain criteria

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

New Listing (Major submission)	SOFOSBUVIR sofosbuvir 400 mg tablet  Sovaldi®  Gilead Sciences Pty Ltd	Hepatitis C	To request Section 100 (Highly Specialised Drugs Program) Public and Private Hospital Authority Required (Streamlined) listing for the treatment of genotypes 1, 2, 3, 4, 5, and 6 hepatitis C viral infection in patients 18 years or older who have compensated liver disease.
Change to Listing (Major submission)	SORAFENIB sorafenib 200mg tablet  Nexavar®  Bayer Australia Ltd	Thyroid Cancer	To request an Authority required listing for the treatment of patients with locally advanced or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine.
Change to Listing (Minor submission)	STRONTIUM strontium ranelate 2 g granules, 28 x 2 g sachets  Protos®  Servier Laboratories (Australia) Pty Ltd	Osteoporosis	To request a change to existing PBS listing for treatment of patients with established osteoporosis to reflect amended TGA indications following a review of safety.
New Listing (Minor submission)	TRIGLYCERIDES LONG CHAIN with GLUCOSE POLYMER triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons  Sno-Pro®  Nutricia Australia Pty Ltd	Medicinal food	To request a Restricted Benefit listing for patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.
New Listing (Minor submission)	TRIGLYCERIDES MEDIUM CHAIN FORMULA Triglycerides medium chain formula oral liquid, powder for, 400 g  Peptamen Junior®  Nestle Health Science	Medicinal food	To request a Restricted Benefit listing for fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

Change to Listing (Minor submission)	TRIVALENT INFLUENZA VACCINE  Office of Health Protection, Department of Health	Influenza	To request an extension of the National Immunisation Program (NIP) schedule to include trivalent influenza vaccine (TIV) for all Aboriginal and Torres Strait Islander children aged between 6 months and 5 years.
New Listing (Major submission)	UMECLIDINIUM BROMIDE umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations  Incruse® 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).
Re-submission (Minor submission)	UMECLIDINIUM BROMIDE + VILANTEROL TRIFENATATE (FDC) umeclidinium bromide 62.5 microgram/actuation + vilanterol trifenate 25 microgram/actuation inhalation: powder for  Anoro™ Ellipta®  GlaxoSmithKline Australia Pty Ltd	Chronic obstructive pulmonary disease	To request a Authority Required (Streamlined) 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 beta2-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.
New Listing (Major submission)	VEDOLIZUMAB vedolizumab 300 mg injection, 1 x 300 mg vial  Entyvio®  Takeda Pharmaceuticals Australia Pty Ltd	Ulcerative colitis (UC)	To request Section 100 (Highly Specialised Drugs Program) Public and Private Hospital Authority Required listing for treatment of moderate to severe ulcerative colitis (UC) in patients who have failed conventional therapies and who meet certain criteria.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
July 2014 PBAC MEETING**

**Closing date for consumer comments 11 June 2014**

<p>Re-submission (Minor submission)</p>	<p>VILDAGLIPTIN vildagliptin 50 mg tablet</p> <p>Galvus®</p> <p>VILDAGLIPTIN + METFORMIN vildagliptin 50 mg + metformin hydrochloride 500 mg tablet vildagliptin 50 mg + metformin hydrochloride 850 mg tablet vildagliptin 50 mg + metformin hydrochloride 1 g tablet</p> <p>Galvumet 50/500® Galvumet 50/850® Galvumet 50/1000®</p> <p>Novartis Pharma AG</p>	<p>Type 2 diabetes</p>	<p>To request extending the current Authority Required (Streamlined) listings of vildagliptin and vildagliptin+metformin fixed dose combination (FDC) tablets to include use in triple combination therapy with metformin and a sulfonylurea (for vildagliptin) and in combination with a sulfonylurea (for vildagliptin+metformin FDC) for the treatment of diabetes mellitus type 2.</p>
<p>New Listing (Minor submission)</p>	<p>VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets</p> <p>FruitiVits®</p> <p>Vitaflo Australia Pty Ltd</p>	<p>Medicinal food</p>	<p>To request an Authority Required listing for children whose vitamin and mineral intake is insufficient due to a specific diagnosis requiring a highly restrictive therapeutic diet, and whose vitamin, mineral and trace element needs cannot be adequately met with other proprietary vitamin and mineral</p>
<p>New Listing (Major submission)</p>	<p>VORTIOXETINE vortioxetine 5 mg tablet vortioxetine 10 mg tablet vortioxetine 15 mg tablet vortioxetine 20 mg tablet</p> <p>Brintellix®</p> <p>Lundbeck Australia Pty Ltd</p>	<p>Major depressive disorders</p>	<p>To request Authority required listing for treatment of major depression disorder in patients aged 18 years or older who have failed to respond to, or are intolerant/contraindicated to other antidepressant therapy</p>