PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2013 PBAC MEETING

Closing date for consumer comments 13 February 2013

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
MARCH 2013 PBAC MEETING

Closing date for consumer comments 13 February 2013

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*
Change to listing (Major submission)	ADALIMUMAB, injection, 40 mg in 0.8 mL pre-filled syringe, 40 mg in 0.8 mL pre-filled pen, Humira® AbbVie Pty Ltd	Chronic plaque psoriasis	Extend the current Authority required listing to include treatment of an adult patient with moderate to severe chronic plaque psoriasis who meets certain criteria.
Re-submission (Minor submission)	ALGLUCOSIDASE alfa-rch, powder for I.V. infusion, 50 mg, Myozyme® Genzyme – A Sanofi Company	Pompe disease	Resubmission for listing on the Life Saving Drugs Program (LSDP) for treatment of children, teenagers and adults with late-onset Pompe disease.
Change to listing New listing (Minor submission)	AMINO ACID FORMULA with VITAMINS and MINERALS (without various amino acids), 'Cooler'® range of products Vitaflo Australia Pty Ltd	Medicinal foods	1) To amend the brand names of currently PBS-listed Coolers to include the grams of protein; 2) To list additional pack sizes for the MSUD, HCU and TYR Cooler ranges with the same restriction as the currently listed Cooler 15; 3) To inform of minor nutritional amendments across the whole Cooler range, including PKU Cooler 10, 15 and 20.
Change to listing (Minor submission)	AMINO ACIDS WITH CARBOHYDRATE (various formulations) Vitaflo Australia Pty Ltd	Medicinal foods	To amend the brand names of currently PBS-listed single dose amino acids with carbohydrate to include amino acid doses, and to advise of packaging changes.
Change to listing (Minor submission)	AMYLOPECTIN MODIFIED LONG CHAIN, oral liquid: powder for, 30 x 60 g sachets, Glycosade® Vitaflo Australia Pty Ltd	Medicinal food	To amend the label to accurately reflect the sodium content.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
MARCH 2013 PBAC MEETING

Closing date for consumer comments 13 February 2013

Re-submission (Minor submission)	BOTULINUM TOXIN TYPE A, 100 units injection, 1 x 100 units vial, Botox® Allergan Pty Ltd	Urinary incontinence	Re-submission for a Section 100 (Botulinum Toxin Program) listing for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) in patients with multiple sclerosis, spinal cord injury or adult spina bifida who meet certain criteria.
Change to listing (Minor submission)	CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE calcipotriol 0.005% (50 microgram/g) + betamethasone (as dipropionate) 0.05% (500 microgram/g) gel, 30 g, Daivobet® Leo Pharma Pty Ltd	Psoriasis	Extend the current Restricted benefit listing to include treatment of chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy. (current listing is for scalp only, extended listing will include body)
New listing (Minor submission)	CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE calcipotriol 0.005% (50 microgram/g) + betamethasone (as dipropionate) 0.05% (500 microgram/g) gel, 60 g, Daivobet® Leo Pharma Pty Ltd	Psoriasis	To request a Restricted benefit listing for a larger size (60 g) for treatment of chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy.
Change to listing (Minor submission)	CLOZAPINE, tablet, 25 mg & 100 mg, Clozaril® Novartis Pharmaceuticals Australia Pty Ltd	Schizophrenia	Requests to change the existing Section 100 Highly Specialised Drugs Program Authority Required (+/- STREAMLINED) listing for treatment of schizophrenia in patients who are non-responsive to or intolerant of other neuroleptic agents to a Section 85 Authority Required listing.
New listing (Major submission)	COBICISTAT, tablet, 150mg, Brand name to be confirmed Gilead Sciences Pty Ltd	Human immunodeficiency virus (HIV) infection	Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority Required (STREAMLINED) listing for treatment of an HIV-infected patient as a pharmacokinetic enhancer of atazanavir.

Closing date for consumer comments 13 February 2013

New listing (Major submission)	COBICISTAT+ELVITEGRAVIR+EMTRICITABINE+TENOFOVIR, tablet, 150 mg-150 mg-200 mg-300 mg, Stribild® Gilead Sciences Pty Ltd	Human immunodeficiency virus (HIV) infection	Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority Required (STREAMLINED) listing for treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease.
Change to listing (Major submission)	CORIFOLLITROPIN ALFA, injection, 150 micrograms in 0.5 mL, Elonva® Merck Sharp & Dohme (Australia) Pty Ltd	Fertility drug	1) Extend the current Section 100 IVF/GIFT Program listing to include treatment of women who weigh over 90 kg; and 2) Review the therapeutic relativity and price compared to follicle stimulating hormone (FSH).
New listing (Major submission)	DABRAFENIB, capsule, 50 mg and 75 mg, Rafinlar ® GlaxoSmithKline Australia Pty Ltd	Melanoma	Authority Required listing for treatment of BRAF V600 mutation positive advanced (unresectable stage III) or metastatic (stage IV) melanoma in a patient with a WHO performance status of 2 or less.
New listing (Minor submission)	DIAZEPAM, oral solution 10 mg/10mL, Orion Diazepam Elixir 10mg/10mL® Orion Laboratories Pty Ltd	Chronic spasticity	Restricted benefit listing for the treatment of chronic spasticity in children.
New listing (Major submission)	ECULIZUMAB, concentrated solution for I.V. infusion, 300 mg in 30 mL, Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	Atypical Haemolytic Uraemic Syndrome (aHUS)	Section 100 Highly Specialised Drugs Program listing or inclusion on the Life Saving Drugs Program (LSDP) for treatment of atypical Haemolytic Uraemic Syndrome (aHUS).
New listing (Major submission)	ELVITEGRAVIR, tablet, 85 mg and 150 mg, Brand name to be confirmed Gilead Sciences Pty Ltd	Human immunodeficiency virus (HIV) infection	Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority Required (STREAMLINED) listing for continuing treatment of HIV infection, in combination with a boosted protease inhibitor and other antiretroviral agents, where the patient has previously received PBS-subsidised therapy for HIV infection.

Closing date for consumer comments 13 February 2013

Change to listing (Major submission)	EPLERENONE, tablet, 25 mg and 50 mg, Inspra® Pfizer Pty Limited	Heart failure	Extend the current Authority Required (STREAMLINED) listing to include treatment of New York Heart Association (NYHA) class II (chronic) heart failure with left ventricular systolic dysfunction (LVEF) in addition to standard optimal therapy.
New listing (Major submission)	ERIBULIN MESILATE, solution for injection, 1 mg in 2 mL, Halaven® Eisai Australia Pty Limited	Breast cancer	Section 100 Efficient Funding of Chemotherapy listing for the treatment of a patient with locally advanced or metastatic breast cancer who has progressed after at least two chemotherapeutic regimens for advanced disease.
New listing (Minor submission)	ESOMEPRAZOLE STRONTIUM TETRAHYDRATE, capsules, 20 mg and 40 mg, Esonova® iNOVA Pharmaceuticals Australia	Gastro-oesophageal reflux disease (GORD)	Authority Required listing for the treatment of gastro-oesophageal reflux disease for 20 mg and 40 mg capsules with bioequivalence to Nexium® 20 mg and 40 mg tablets.
New listing (Major submission)	EVEROLIMUS, tablet, 5 mg and 10 mg, Afinitor® Novartis Pharmaceuticals Australia Pty Ltd	Breast cancer	Authority Required listing for treatment, in combination with an aromatase inhibitor, of post-menopausal women with hormone-receptor positive, HER2 negative advanced breast cancer after failure of treatment with letrozole or anastrozole.
New listing (Major submission)	FENTANYL, single dose spray 6-pack, 50 micrograms, 100 micrograms and 200 micrograms; 10-dose spray bottle, 50 micrograms, 100 micrograms and 200 micrograms; 20-dose spray bottle, 50 micrograms, 100 micrograms and 200 micrograms, Instanyl® Takeda Pharmaceuticals Australia Pty Ltd	Pain	Palliative Care Schedule listing for treatment of breakthrough pain in a patient with cancer who is receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.
New listing (Major submission)	FERRIC CARBOXYMALTOSE, injection, 100 mg in 2 mL and 500 mg in 10 mL, Ferinject® Vifor Pharma Pty Ltd	Anaemia	Authority Required listing for treatment of iron deficiency anaemia, where oral iron preparations are not tolerated, ineffective or otherwise inappropriate.

Closing date for consumer comments 13 February 2013

New listing (Minor submission)	FILGRASTIM, 300 µg/0.5 mL & 480 µg/0.5 mL solution for injection in pre-filled syringe, Zarzio® Sandoz Pty Ltd	Immunostimulant	Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority required (STREAMLINED) listings for a new brand of filgrastim products biosimilar to currently listed filgrastim pre-filled syringes (Neupogen®).
New listing (Minor submission)	GLUCOSE INDICATOR BLOOD, glucose indicator blood strip: diagnostic, 50 diagnostic strips, OneTouch®Select® Johnson & Johnson Medical Pty Ltd	Blood glucose monitoring	To request an unrestricted listing, and a restricted benefit listing for use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements of a new brand of test strips.
New listing (Minor submission)	HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW IN PROTEIN and CARBOHYDRATE, Ketocal 3:1 Nutricia Australia Pty Ltd	Medicinal food	Restricted benefit for treatment of an infant or young child up to the age of 6 years (as a sole source of nutrition); or a child over 6 years (as a supplementary feed) with: - intractable seizures requiring treatment with a ketogenic diet - Glucose transporter protein defects (GLUT-1) - Pyruvate Dehydrogenate Deficiency (PDH)
Change to listing (Major submission)	INFLIXIMAB, powder for IV infusion, 100mg, Remicade® Janssen Pty Ltd	Ulcerative colitis	Extend the current Section 100 Highly Specialised Drugs Program Public and Private Hospital Authority Required listings to include treatment of acute severe ulcerative colitis not responding to IV corticosteroids in a patient aged 6 years or greater and who meets certain criteria.
New listing (Major submission)	INSULIN DEGLUDEC, injection, 100 units per mL and 200 units per mL, 3 mL, Tresiba FlexTouch®; injection, 100 units per mL, 3 mL, Tresiba Penfill® Novo Nordisk Pharmaceuticals Pty Ltd	Diabetes	Unrestricted listing (for use in the treatment of patients with type 1 or 2 diabetes).

Closing date for consumer comments 13 February 2013

Re-submission (Minor submission)	IVABRADINE, tablet, 5 mg and 7.5 mg (as hydrochloride), Coralan® Servier Laboratories (Australia) Pty Ltd	Heart failure	Re-submission for an Authority Required listing for the treatment of symptomatic systolic chronic heart failure (NYHA classes II or III) in patients in sinus rhythm, with a resting heart rate of at least 77 bpm, measured after 5 minutes rest, who are stabilised on optimal heart failure.
Re-submission (Major submission)	LENALIDOMIDE, capsule, 5 mg and 10 mg, Revlimid® Celgene Pty Ltd	Myelodysplastic syndrome (MDS)	Re-submission to extend the current Section 100 Highly Specialised Drugs Program Public and Private Hospital Authority Required listings to include treatment of a patient with low or intermediate-1 myelodysplastic syndrome (MDS) with a deletion 5q abnormality who is transfusion dependent.
Change to listing (Minor submission)	LENALIDOMIDE, capsule, 5 mg and 10 mg, Revlimid® Celgene Pty Ltd	Multiple myeloma	Amend the current Section 100 Highly Specialised Drugs Program Public and Private Hospital Authority Required listings to remove the requirement for prior treatment with thalidomide in multiple myeloma patients with progressive disease.
New listing (Minor submission)	LEVONORGESTREL + ETHINYLOESTRADIOL levonorgestrel 100 microgram + ethinyloestradiol 20 microgram tablet [63 tablets] (&) inert substance tablet [21 tablets], 84 [3 x 28 tablets], Loette® Pfizer Australia Pty Ltd	Oral contraceptive and acne treatment	To request an Unrestricted benefit listing (for use as an oral contraceptive and acne treatment).
New listing (Major submission)	LINAGLIPTIN + METFORMIN, tablet, 2.5 mg-500 mg, 2.5 mg-850 mg and 2.5 mg-1000 mg, Brand name to be confirmed Boehringer Ingelheim Pty Ltd	Diabetes	Authority Required (STREAMLINED) listing for treatment of type 2 diabetes in a patient whose HbA_{1c} is greater than 7% prior to initiation of a gliptin, glitazone or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated (dual oral therapy).

Closing date for consumer comments 13 February 2013

Re-submission (Major submission)	LIRAGLUTIDE, solution for injection, 6 mg per mL, Victoza® Novo Nordisk Pharmaceuticals Pty Ltd	Diabetes	Re-submission for an Authority Required listing for treatment of type 2 diabetes as: 1) Dual combination therapy with metformin or a sulphonylurea; and 2) Triple combination therapy with metformin and a sulphonylurea.
Change to listing (Minor submission)	MANNITOL, capsule containing powder for oral inhalation, 40 mg (for use in inhaler device), Bronchitol® Pharmaxis Ltd	Cystic fibrosis	Amend the continuation rule to simplify the current Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority required (STREAMLINED) listing for treatment of Cystic Fibrosis.
New listing (Major submission)	MIFEPRISTONE, tablet, 200 mg, Mifepristone Linepharma®; MISOPROSTOL, tablet, 200 microgram, GyMiso® Marie Stopes (MS) Health	Medical termination of a developing intra-uterine pregnancy	Authority Required listing for use in women of childbearing age for the termination of an intra-uterine pregnancy of up to 49 days gestation.
Re-submission (Minor submission)	MIGLUSTAT, capsule, 100 mg, Zavesca® Actelion Pharmaceuticals Australia Pty Ltd	Niemann Pick Disease Type-C	Re-submission for inclusion on the Life Saving Drugs Program (LSDP) for the treatment of Niemann Pick Disease Type-C.
New listing (Minor submission)	MOMETASONE FUROATE 0.1% (1 mg/g) hydrogel, 15 g, Zatamil® Ego Pharmaceuticals Pty Ltd	Skin lesions	Restricted benefit listing for a 15 g hydrogel formulation for treatment of corticosteroid-responsive dermatoses.
New listing (Minor submission)	MOMETASONE FUROATE 0.1% (1 mg/g) hydrogel, 45 g, and ointment 45 g, Zatamil® Ego Pharmaceuticals Pty Ltd	Skin lesions	Restricted benefit listing for 45 g hydrogel and ointment formulations for treatment of corticosteroid-responsive dermatoses.

Closing date for consumer comments 13 February 2013

Re-submission (Major submission)	PANITUMUMAB, concentrated solution for infusion, 20 mg per mL, 5 mL, Vectibix® Amgen Australia Pty Ltd	Colorectal cancer	Re-submission for Section 100 Efficient Funding of Chemotherapy Private Hospital Authority Required and Public Hospital Authority required (STREAMLINED) listings for: 1) Treatment, as monotherapy or in combination with FOLFIRI, of a patient with a WHO performance status of 2 or less and with a KRAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; and 2) Treatment, in combination with FOLFOX, of a patient with a WHO performance status of 2 or less with previously untreated KRAS wild-type metastatic colorectal cancer where treatment with bevacizumab is unsuitable.
Re-submission (Minor submission)	PEGINTERFERON ALFA-2A (&) RIBAVIRIN, peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack; peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack; peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack; peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack; Pegasys RBV® Roche Products Pty Ltd	Hepatitis C	Re-submission for Section 100 Private Hospital Authority required and Public Hospital Authority required (STREAMLINED) listings for the same chronic hepatitis C indications as the current Pegasys RBV combination packs.
New listing (Minor submission)	PROTEIN HYDROLYSATE FORMULA, powder, 900 g, Karicare Aptamil Gold+ Allerpro 1® Nutricia Australia Pty Ltd	Medicinal food	Authority required listing for cows' milk protein enteropathy in infants up to12 months of age.
New listing (Minor submission)	PROTEIN HYDROLYSATE FORMULA, powder, 900 g, Karicare Aptamil Gold+ Allerpro 2® Nutricia Australia Pty Ltd	Medicinal food	Authority required listing for cows' milk protein enteropathy and intolerance to soy protein in infants 6 to 24 months of age.

Closing date for consumer comments 13 February 2013

New listing (Minor submission)	RALTEGRAVIR, chewable tablet, 25 mg and 100 mg, Isentress® Merck Sharp & Dohme (Australia) Pty Ltd	HIV infection	Section 100 Highly Specialised Drugs Program Private Hospital Authority required and Public Hospital Authority required (STREAMLINED) listing for treatment of HIV-1 infection in adolescents and children from 2 years of age, or weighing at least 10 kg.
Change to listing (Major submission)	RANIBIZUMAB, solution for intravitreal injection, 2.3 mg in 0.23 mL, Lucentis® Novartis Pharmaceuticals Australia Pty Ltd	Visual impairment	Extend the current Authority required listing to include treatment, by an ophthalmologist, of a patient with visual impairment due to diabetic macular oedema, as diagnosed by fluorescein angiography.
Matters arising from the Minutes	REVIEW OF ANTICOAGULATION THERAPIES IN ATRIAL FIBRILLATION	Anti-coagulation	To consider updated analyses of the novel oral anti-coagulant drugs in response to the findings of the Review of Anticoagulation Therapies in Atrial Fibrillation.
Change to listing (Major submission)	RISEDRONATE SODIUM, tablet 5 mg, Actonel®, tablet 35 mg (enteric coated), Actonel EC®, tablet 150 mg, Actonel Once-a-Month®; RISEDRONATE SODIUM and CALCIUM CARBONATE, pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), Actonel Combi®, pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), Actonel EC Combi®; RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL, pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, Actonel EC Combi D® Sanofi-aventis Australia Pty Ltd	Osteoporosis	Extend the current Authority required (STREAMLINED) listing to include treatment of a patient aged 70 years of age or older with a BMD T-score less than or equal to -2.5.

Closing date for consumer comments 13 February 2013

Change to listing (Minor submission)	RISEDRONATE risedronate sodium 35 mg tablet, 4, Acris® RISEDRONATE (&) CALCIUM CARBONATE risedronate sodium 35 mg tablet [4 tablets] (&) calcium (as carbonate) 500 mg tablet [24 tablets], 28, Acris Combi® Alphapharm Pty Ltd	Osteoporosis	To request a brand equivalence indicator be applied between the immediate release tablet formulations and the enteric coated formulations containing risedronate 35 mg (Actonel EC® and Actonel EC Combi®).
Change to listing (Minor submission)	RISEDRONATE SODIUM, tablet, 35 mg (enteric coated), Actonel EC®; RISEDRONATE SODIUM and CALCIUM CARBONATE, pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), Actonel EC Combi® Sanofi-Aventis Australia Pty Ltd	Osteoporosis	Request that these products not be deemed to be equivalent for the purposes of substitution to other immediate release risedronate products on the PBS.
Change to listing (Minor submission)	RISEDRONATE SODIUM, tablet, 35 mg, Risedro Once a Week® Aspen Pharma Pty Ltd	Osteoporosis	To request a brand equivalence indicator be applied between the immediate release tablet and the enteric coated formulation of risedronate 35 mg (Actonel EC®)
Change to listing (Major submission)	RIVAROXABAN, tablet, 15 mg and 20 mg, Xarelto® Bayer Australia Ltd	Anticoagulant	Extend the current Authority required (STREAMLINED) listing to include treatment of acute symptomatic pulmonary embolism (PE) and prevention of recurrent venous thromboembolism (VTE).
New listing (Major submission)	SAXAGLIPTIN WITH METFORMIN, tablet, 2.5 mg-500 mg, 2.5 mg-850 mg, 2.5 mg-1000 mg, Kombiglyze® Bristol-Myers Squibb Australia Pty Ltd	Diabetes	Authority required (STREAMLINED) listing for treatment of type 2 diabetes in a patient whose HbA_{1c} is greater than 7% prior to initiation of a gliptin, glitazone or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated (dual oral therapy).

Closing date for consumer comments 13 February 2013

Change to listing (Minor submission)	SORAFENIB, tablet, 200 mg, Nexavar® Bayer Australia Limited	Liver cancer	Request to change the current Authority required listing for initial and continuing treatment of hepatocellular carcinoma to an Authority required (STREAMLINED) listing.
Change to listing (Minor submission)	TESTOSTERONE, topical solution for transdermal application, 30 mg in 1.5 mL, Axiron® Eli Lilly Australia Pty Ltd	Testosterone replacement therapy	Seeks review of the March 2012 recommended relativity ratio between testosterone solution and testosterone gel.
New listing (Major submission)	TOBRAMYCIN, powder for inhalation, capsule 28 mg, Tobi® Podhaler® Novartis Pharmaceuticals Australia Pty Ltd	Cystic fibrosis	Authority required (STREAMLINED) listing for management of a proven *Pseudomonas aeruginosa* infection in a patient aged 6 years or older with cystic fibrosis.
Re-submission (Major submission)	VEMURAFENIB, tablet, 240 mg, Zelboraf® Roche Products Pty Ltd	Melanoma	Re-submission for an Authority required listing for initial and continuing treatment of previously untreated, unresectable, stage IIIC or stage IV, BRAF V600 mutation positive metastatic melanoma with a WHO performance status of less than or equal to 2.
Re-submission (Minor submission)	VINORELBINE, capsule, 20 mg and 30 mg, Navelbine® Pierre Fabre Medicament	Breast cancer	Re-submission for an Authority required listing for treatment of advanced breast cancer after failure of standard prior therapy which includes an anthracycline, as a single agent or in combination.