

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
JULY 2011 PBAC MEETING**

**Closing date for consumer comments 8 June 2011**

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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<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)	ABATACEPT (rch), powder for I.V. infusion, 250mg, Orencia <sup>®</sup>  Bristol-Myers Squibb Australia Pty Ltd	Juvenile arthritis	Extend the current Authority Required Section 100 (Highly Specialised Drug) listing to include the treatment of severe active juvenile idiopathic arthritis (JIA) in patients who have severe intolerance of, or toxicity due to, methotrexate or who have failed to achieve an adequate response to methotrexate.
New drug application  (Minor submission)	ABATACEPT, injections 125 mg in 1 mL single use pre-filled syringes, 4, Orencia <sup>®</sup>  Bristol-Myers Squibb Australia Pty Ltd	Arthritis	Authority Required listing for a subcutaneous form for the treatment of adult rheumatoid arthritis.
Resubmission  (Major submission)	AGOMELATINE, tablet, 25mg, Valdoxan <sup>®</sup>  Servier Laboratories (Australia) Pty Ltd	Anti-depressant	Restricted Benefit listing for major depressive disorders.
Resubmission  (Major submission)	ALENDRONATE SODIUM, tablet equivalent to 70 mg alendronic acid, Fosamax Once Weekly <sup>®</sup> , ALENDRONATE SODIUM with COLECALCIFEROL, tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol, Fosamax Plus <sup>®</sup> , ALENDRONATE SODIUM with COLECALCIFEROL tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol, Fosamax Plus 70 mg/140 mcg <sup>®</sup> , ALENDRONATE SODIUM with COLECALCIFEROL and CALCIUM CARBONATE, pack containing 4 tablets containing the equivalent of 70 mg alendronic acid with 140 micrograms colecalciferol and 48 tablets calcium carbonate 1.25 g (equivalent to 500 mg elemental calcium), Fosamax Plus D-Cal <sup>®</sup>  Merck, Sharp & Dohme (Australia) Pty Ltd	Osteoporosis	Extend the current Authority Required (STREAMLINED) listing to include treatment of osteoporosis in patients aged 70 years or older with a bone mineral density (BMD) T-score of -2.5 or less.

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Resubmission (Major submission)	ALGLUCOSIDASE alfa-rch, powder for I.V. infusion, 50 mg, Myozyme <sup>®</sup>  Genzyme Australasia Pty Ltd	Pompé disease	Section 100 (Highly Specialised Drugs) listing or inclusion on the Life Saving Drugs Program for the treatment of patients with late-onset Pompé disease.
New drug application (Major submission)	APIXABAN, tablet, 2.5 mg, Eliquis <sup>®</sup>  Bristol-Myers Squibb Australia Pty Ltd	Anticoagulant	Authority required listing for prevention of venous thromboembolism in a patient undergoing total knee replacement or total hip replacement.
New drug application (Major submission)	ASENAPINE, sublingual wafer, 5 mg, 10 mg (as maleate), Saphris <sup>®</sup>  Lundbeck Australia Pty Ltd	Bipolar disorder	Authority required (STREAMLINED) listing for treatment of bipolar I disorder.
New drug application (Major submission)	ASENAPINE, sublingual wafer, 5 mg, 10 mg (as maleate), Saphris <sup>®</sup>  Lundbeck Australia Pty Ltd	Schizophrenia	Authority required (STREAMLINED) listing for treatment of schizophrenia.
New drug application (Major submission)	BOCEPRAVIR, capsule, 200 mg, Victrelis <sup>®</sup>  Merck, Sharp & Dohme (Australia) Pty Ltd	Hepatitis C	Section 100 (Highly Specialised Drugs) Authority required listing for treatment of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who are naïve or who have failed one prior attempt with interferon alfa or peginterferon alfa treatment for hepatitis C and meet certain criteria.
Change to listing (Minor submission)	BORTEZOMIB, powder for injection 1 mg (solvent required), Velcade <sup>®</sup>  Janssen-Cilag Pty Ltd	Anti-cancer drug	Extend the current Authority required listing to include treatment of patients with newly diagnosed symptomatic multiple myeloma who have severe acute renal failure and who meet certain criteria.
New drug application (Major submission)	CABAZITAXEL, solution concentrate for I.V. infusion, 60 mg in 1.5 mL, Jevtana <sup>®</sup>  Sanofi-Aventis Australia Pty Ltd	Anti-cancer drug	Authority required listing for treatment of hormone refractory metastatic carcinoma of the prostate in patients previously treated with a docetaxel containing regimen.

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Change to listing (Major submission)	CLOSTRIDIUM BOTULINUM type A toxin-haemagglutinin complex, lyophilised powder for I.M. injection, 300 units per vial, 500 units per vial, Dysport®  Ipsen Pty Ltd	Spasticity	Extend the current Section 100 (Botulinum Toxin Program) listing for treatment of blepharospasm and hemifacial spasm in adults.  List a new 300 units per vial strength presentation of Dysport.
Resubmission (Minor submission)	COLISTIMETHATE SODIUM, powder for nebuliser solution, 1 million IU (equivalent to 80 mg colistimethate sodium), Tadin®  Phebra Pty Ltd	Anti-infective/cystic fibrosis	Authority required listing for treatment of <i>Pseudomonas aeruginosa</i> infection in a patient with cystic fibrosis.
Resubmission (Major submission)	CORIFOLLITROPIN ALFA(rch), solution for injection, 100 micrograms in 0.5 mL pre-filled syringe, 150 micrograms in 0.5 mL pre-filled syringe, Elonva®  Schering-Plough Pty Ltd (MSD)	Fertility drug	Section 100 (IVF/GIFT Program) listing for patients who are receiving medical treatment as described in items 13200, 13201 or 13202 of the Medicare Benefits Schedule.
New drug application (Minor submission)	DARUNAVIR, tablet 400 mg and 600 mg (as ethanolate), Prezista®  Janssen-Cilag Pty Ltd	Anti-viral for HIV	Section 100 (Highly Specialised Drugs Program) Authority required listing of two higher strengths for treatment of HIV infection.
Change to listing (Major submission)	DASATINIB, tablet, 20 mg, 50 mg, 70 mg, 100 mg, Sprycel®  Bristol-Myers Squibb Australia Pty Ltd	Anti-cancer drug	Extend the current Authority Required listing to include treatment of newly diagnosed patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia.
New drug application (Major submission)	DENOSUMAB, injection, 120 mg in 1 mL, Xgeva®  Amgen Australia Pty Ltd	Cancer related bone metastases	Authority required (STREAMLINED) listing for treatment of bone metastases from breast cancer and hormone resistant prostate cancer.
Change to listing (Major submission)	DIPHtheria, TETANUS, & ACELLULAR PERTUSSIS (dTpa), injection, 0.5mL, Boostrix®  GlaxoSmithKline Australia Pty Ltd	Vaccine	Extend the current National Immunisation Program listing to include active vaccination of both parents of newborn infants, where there is no documented evidence of a dTpa booster having been given in the previous 10 years.

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Resubmission (Major submission)	DRONEDARONE, tablet, 400 mg (as hydrochloride), Multaq <sup>®</sup>  Sanofi-Aventis Australia Pty Ltd	Atrial fibrillation	Resubmission for an Authority Required (STREAMLINED) listing for the prevention of recurrence of atrial fibrillation or flutter.
New drug application (Major submission)	ESOMEPRAZOLE 20 mg (as magnesium trihydrate), with NAPROXEN 500 mg, tablet, Vimovo <sup>®</sup>  AstraZeneca Pty Ltd	Arthritis	Restricted benefit listing for treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing non-steroidal anti-inflammatory drugs (NSAID) associated gastric and/or duodenal ulcers.
New drug application (Major submission)	EXENATIDE, powder for injection, 2 mg, Bydureon <sup>®</sup>  Eli Lilly Australia Pty Ltd	Type 2 diabetes	Authority required listing for treatment of type 2 diabetes mellitus in combination with metformin or a sulfonylurea or triple combination therapy with metformin and a sulfonylurea.
Resubmission (Major submission)	ICATIBANT, injection, 30 mg in 3 mL (as acetate), single use pre-filled syringe, Firazyf <sup>®</sup>  Shire Australia Pty Ltd	Acute hereditary angioedema (a condition causing swelling)	Authority Required listing for anticipated emergency treatment of an acute attack hereditary angioedema in a patient with confirmed diagnosis of C1-esterase inhibitor deficiency.
Resubmission (Major submission)	INDACATEROL, capsule containing powder for oral inhalation, 150 microgram and 300 microgram (as maleate), Onbrez <sup>®</sup>  Novartis Pharmaceuticals Australia Pty Ltd	Chronic obstructive pulmonary disease	Restricted benefit listing for long-term maintenance treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease.
Change to listing (Minor submission)	INTERFERON BETA-1a, injection set comprising 1 vial powder for injection 30 micrograms (6,000,000 i.u.) with diluent; injection 30 micrograms (6,000,000 i.u.) in 0.5 mL single dose pre-filled syringe, Avonex <sup>®</sup>  Biogen Idec Australia Pty Ltd	Multiple sclerosis	Request to change the current Authority required listing for relapsing-remitting multiple sclerosis to Authority required (STREAMLINED)
New drug application (Major submission)	IPILIMUMAB, concentrate for I.V infusion, 50 mg in 10 mL, 200 mg in 40 mL, Yervoy <sup>®</sup>  Bristol-Myers Squibb Australia Pty Ltd	Anti-cancer drug	Section 100 (Highly Specialised Drugs) Authority required listing for treatment of patients with unresectable stage III or stage IV malignant melanoma who have not responded to or were intolerant to prior systemic therapy for metastatic disease.

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Resubmission (Minor submission)	LLENALIDOMIDE, capsule, 5 mg, 10 mg, 15 mg and 25 mg, Revlimid <sup>®</sup>  Celgene Pty Ltd	Anti-cancer drug	Extend the current Section 100 (Highly Specialised Drugs Program) Authority required listing to include use in the treatment of patients with transfusion dependent low risk/INT-1-5q myelodysplastic syndrome.
New drug application (Major submission)	LINAGLIPTIN, tablet, 5 mg, Ondero <sup>®</sup> /Trajenta <sup>®</sup>  Boehringer Ingelheim Pty Ltd	Type 2 diabetes	Authority required (STREAMLINED) listing for treatment of patients with type 2 diabetes in combination with metformin or a sulphonylurea.
Resubmission (Minor submission)	LIRAGLUTIDE (rys), solution for injection, 3 mL pre-filled injection pen, 6 mg per mL, Victoza <sup>®</sup>  Novo Nordisk Pharmaceuticals Pty Ltd	Type 2 diabetes	Re-submission for an Authority required listing for treatment of type 2 diabetes: 1) as triple combination therapy with metformin and a sulphonylurea; 2) as dual combination therapy with metformin or a sulphonylurea in patients for whom a combination of metformin and a sulphonylurea is contraindicated or not tolerated.
New drug application (Minor submission)	MAGNESIUM ASPARTATE, tablet 500 mg, MagMin <sup>®</sup>  Blackmores Ltd	Hypomagnesaemia	Restricted benefit for patients with chronic renal failure to treat hypomagnesaemia
New drug application (Minor submission)	MAGNESIUM ASPARTATE, tablet 500 mg, Mag-Sup <sup>®</sup>  Petrus Pharmaceuticals Pty Ltd	Hypomagnesaemia	Restricted benefit listing for patients with documented hypomagnesaemia
New drug application (Minor submission)	MOMETASONE FUROATE, powder for oral inhalation, 200 micrograms/dose and 400 micrograms/dose, Asmanex <sup>®</sup> Twisthaler <sup>®</sup>  Merck Sharp & Dohme (Australia) Pty Ltd	Asthma	Request to reinstate the June 2002 PBAC recommendation for an unrestricted benefit listing.
New drug application (Minor submission)	NEVIRAPINE, tablet 400 mg (extended release), Viramune XR <sup>®</sup>  Boehringer-Ingelheim Pty Ltd	Anti-viral for HIV	Section 100 (Highly Specialised Drugs Program) Authority required listing of an extended-release form for treatment of HIV infection in combination with other antiretroviral agents.

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New drug application (Minor submission)	NICOTINE, transdermal patch, releasing approximately 14 mg per 24 hours, Nicotinell Step 2 <sup>®</sup> ; releasing approximately 7 mg per 24 hours, Nicotinell Step 3 <sup>®</sup>  Novartis Consumer Health Australasia Pty Ltd	Smoking cessation	Authority required listing of two additional (lower) strengths of nicotine patch.
Change to listing (Major submission)	NILOTINIB, capsule, 150 mg (as hydrochloride), Tasigna <sup>®</sup>  Novartis Pharmaceuticals Australia Pty Ltd	Anti-cancer drug	Extend the current Authority required listing to include treatment of newly diagnosed patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia.
New drug application (Minor submission)	PRAMIPEXOLE, tablet, 2.25 mg and 3.75 mg (extended release), Sifrol ER <sup>®</sup>  Boehringer-Ingelheim Pty Ltd	Parkinson disease	Restricted benefit listing of two additional strengths for treatment of Parkinson disease.
New drug application (Major submission)	RASAGILINE, tablet, 1 mg (as mesylate), Azilect <sup>®</sup>  Lundbeck Australia Pty Ltd	Parkinson disease	Authority required (STREAMLINED) listing for treatment of Parkinson disease as adjunctive therapy in patients being treated with levodopa-decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect.

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<p>Change to listing  (Major submission)</p>	<p>RIBAVIRIN and PEGINTERFERON ALFA-2b, pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent; pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent; pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent; pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent; pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent; pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent, Pegatron<sup>®</sup></p> <p>Schering Plough Pty Ltd</p>	<p>Hepatitis C</p>	<p>Extend the current Section 100 (Highly Specialised Drugs) listing to include treatment of chronic hepatitis C in children and adolescents with a bodyweight of greater than or equal to 27 kg with compensated liver disease and who have not received previous interferon treatment.</p>
<p>New drug application  (Major submission)</p>	<p>ROFLUMILAST, tablet, 500 microgram, Daxas<sup>®</sup></p> <p>Nycomed Pty Ltd</p>	<p>Chronic obstructive pulmonary disease</p>	<p>Restricted benefit listing for maintenance treatment of severe chronic obstructive pulmonary disease in adult patients with chronic bronchitis and a recent history of exacerbations, in combination with long acting bronchodilator treatment.</p>
<p>Change to listing  (Major submission)</p>	<p>SOMATROPIN, injection in 1 mL cartridge (with preservative) 5 mg, 12 mg, Genotropin<sup>®</sup>; powder for injection with diluent in pre-filled pen (with preservative), 5 mg, 12 mg, Genotropin GoQuick<sup>®</sup>; injection with diluent in single use syringe (without preservative) in strengths from 0.6 mg – 2 mg, Genotropin MiniQuick<sup>®</sup></p> <p>Pfizer Australia Pty Ltd</p>	<p>Growth hormone</p>	<p>Extend the current Section 100 (Human Growth Hormone Program) listing to include treatment of adults with severe growth hormone deficiency.</p>
<p>Change to listing  (Major submission)</p>	<p>SUNITINIB, capsule, 12.5 mg, 25 mg and 50 mg (as malate), Sutent<sup>®</sup></p> <p>Pfizer Australia Pty Ltd</p>	<p>Anti-cancer drug</p>	<p>Extend the current Authority required listing to include treatment of unresectable, well-differentiated pancreatic neuroendocrine tumour in patients who are unsuitable for cytotoxic chemotherapy.</p>

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New drug application (Major submission)	T AFLUPROST, eye drops (preservative-free), 15 micrograms per mL, Saflutan <sup>®</sup>  Merck Sharp & Dohme (Australia) Pty Ltd	Anti-glaucoma drug	Unrestricted benefit listing on the General and Optometrical Schedules, used for the treatment of ocular hypertension and primary open-angle glaucoma.
New drug application (Major submission)	T ICAGRELOR, tablet, 90mg, Brilinta <sup>®</sup>  AstraZeneca Pty Ltd	Prevention of heart attack and angina	Authority Required (STREAMLINED) listing for treatment of acute coronary syndromes (myocardial infarction or unstable angina) in combination with aspirin.
Change to listing (Major submission)	T RASTUZUMAB, powder for I.V. infusion, 60 mg, 150 mg, Herceptin <sup>®</sup>  Roche Products Pty Ltd	Anti-cancer drug	Extend the current Authority required listing to include treatment of HER2 positive, advanced (equivalent to stage III or IV) adenocarcinoma of the stomach or gastro-oesophageal junction, in patients who meet certain criteria.
Change to listing (Minor submission)	Z OLEDRONIC ACID, solution for I.V. infusion 5 mg (as monohydrate) in 100 mL, Aclasta <sup>®</sup>  Novartis Pharmaceuticals Australia Pty Ltd	Osteoporosis	Request to remove the 3-year treatment limit for treatment of patients with osteoporosis.