

MARCH 2010 PBAC MEETING OUTCOMES - Positive recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
<p>Adalimumab, injection, 20 mg in 0.4 mL, 40 mg in 0.8 mL, pre-filled syringe, pre-filled pen, Humira®.</p> <p>Abbott Australasia Pty Ltd.</p> <p>Major submission.</p>	<p>Juvenile arthritis</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for treatment of patients under 18 years who have severe polyarticular course juvenile chronic arthritis who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis compared with etanercept. The equi-effective doses estimated using the fixed dose regimen specified in the Product Information and used in the open label extension phase of trial DE038, are adalimumab: 15 kg to less than 30 kg 20 mg, and greater than or equal to 30 kg 40 mg every second week compared with etanercept: 0.4 mg/kg up to 25 mg twice weekly.</p>
<p>Adrenaline, I.M. injection, 300 microgram in 0.3 mL single dose syringe auto-injector, Anapen®, 150 microgram in 0.3 mL single dose syringe auto-injector, Anapen Junior®</p> <p>Link Medical Products Pty Ltd</p> <p>Minor submission.</p>	<p>Severe, allergic reactions</p>	<p>List two strengths of a new form of adrenaline auto-injector.</p>	<p>The PBAC recommended listing on a cost minimisation basis with adrenaline I.M. injection single dose syringe auto-injector (EpiPen). The equi-effective doses are one Anapen and one EpiPen.</p>
<p>Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, 20 g sachets, MMA/PA Express®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Restricted benefit listing for methylmalonic acidemia and propionic acidemia.</p>	<p>Recommended for listing on the same cost basis per gram of protein as XTMVI Maxamaid.</p>

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<p>Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, 20 g sachets, MMA/PA Gel®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Restricted benefit listing for methylmalonic acidaemia and propionic acidaemia.</p>	<p>Recommended for listing on the same cost basis per gram of protein as XTMVI Maxamaid.</p>
<p>Aprepitant, pack containing 1 capsule 125 mg and 2 capsules 80 mg, Emend®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Minor submission</p>	<p>Anti-emetic, anti-nauseant</p>	<p>Re-submission to extend the current listing to include management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy where the patient has had a prior episode of chemotherapy induced nausea or vomiting (i.e. secondary prophylaxis).</p>	<p>The PBAC recommended extending the listing on a cost minimisation basis with standard antiemetic therapy including a 5HT3 antagonist and a corticosteroid (dexamethasone).</p>
<p>Botulinum toxin type A purified neurotoxin complex, lyophilised powder for IM injection 100 units, Botox®</p> <p>Allergan Australia Pty Ltd</p> <p>Minor submission</p>	<p>Excessive sweating</p>	<p>Re-submission to extend the current Section 100 (Botulinum Toxin Program) listing to include treatment of severe primary axillary hyperhidrosis in adult and adolescent patients (> 12 years of age) who meet certain criteria and have failed or are intolerant to topical aluminium chloride hexahydrate.</p>	<p>The PBAC recommended extension to the listing on a cost-effectiveness basis over placebo.</p>

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<p>Brimonidine tartrate with timolol maleate, eye drops, 2 mg -5 mg (base) per mL (0.2%-0.5%), 5 mL, Combigan®</p> <p>Allergan Australia Pty Ltd</p> <p>Minor submission</p>	<p>Glaucoma</p>	<p>Change to the restriction wording.</p>	<p>The PBAC recommended a restriction wording of "elevated intra-ocular pressure in a patient with open angle glaucoma/ocular hypertension not adequately controlled with monotherapy" be applied to all restricted benefit listings of combination eye drops containing an alpha-agonist with timolol, a carbonic anhydrase inhibitor with timolol or a prostaglandin/prostamide analogue with timolol.</p>
<p>Brinzolamide with timolol maleate, eye drops, 10 mg-5 mg (base) per mL, (1%-0.5%), Azarga®</p> <p>Alcon Australia Laboratories (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Glaucoma</p>	<p>Restricted benefit listing in the General and Optometrical Schedules for reduction of elevated intra-ocular pressure in patients with either open-angle glaucoma or ocular hypertension who are not adequately controlled with timolol 5 mg/mL eye drops.</p>	<p>The PBAC recommended listing in the General and Optometrical Schedules on a cost-minimisation basis against the individual components given concurrently and against the combination product dorzolamide 2 % (base) with timolol 0.5 % (base) eye drops (Cosopt). The equi-effective doses for the purposes of cost-minimisation are one drop of the combination brinzolamide with timolol eye drops is equi-effective to one drop of brinzolamide 1 % eye drops plus one drop of timolol 0.5 % eye drops; and that one drop of the combination brinzolamide with timolol eye drops (Azarga) is equi-effective to one drop of the combination dorzolamide with timolol eye drops (Cosopt).</p>
<p>Capecitabine, tablet, 150 mg, 500 mg, Xeloda®</p> <p>Roche Products Pty Ltd</p> <p>Major submission</p>	<p>Cancer treatment</p>	<p>Authority required listing to treat, in combination with a cisplatin-based regimen, of a patient with previously untreated advanced oesophago-gastric cancer with a WHO status of 2 or less.</p>	<p>The PBAC recommended listing on a cost-minimisation basis with 5-fluorouracil. The equi-effective doses are capecitabine 625 mg/m² twice daily and 5-fluorouracil 200 mg/m² per day (triplet therapy) and capecitabine 1000 mg/m² twice daily for 14 days of each 3 week cycle and 5-fluorouracil 800 mg/m² continuous infusion day 1 to 5 of each 3 week cycle (doublet therapy).</p>

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<p>Cephazolin, powder for injection, 2 g, Cefazolin Sandoz®</p> <p>Sandoz Pty Ltd</p> <p>Minor submission (Out of Session)</p>	<p>Anti-infective</p>	<p>List a new, higher strength of this drug.</p>	<p>The PBAC recommended the listing of a new 2 g strength of cephazolin with the same restrictions as the existing 500 mg and 1 g strengths listed on the PBS, on the basis of price parity with existing strengths.</p>
<p>Certolizumab pegol, injection, 200 mg in 1 mL single use pre-filled syringe, Cimzia®</p> <p>UCB Australia Pty Ltd</p> <p>Major submission</p>	<p>Monoclonal antibody for use in rheumatoid arthritis and other chronic inflammatory diseases.</p>	<p>Authority required listing for the treatment of adult patients with severe active rheumatoid arthritis who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis with adalimumab on drug costs alone. The equi-effective doses are certolizumab 400 mg at weeks 0, 2, 4 followed by 200 mg every 2 weeks or 400 mg every 4 weeks and adalimumab 40 mg administered every 2 weeks.</p>
<p>Clopidogrel, tablet, 75 mg (as besilate), Clovix 75®</p> <p>Sigma Pharmaceuticals (Australia) Pty Ltd</p> <p>Minor submission</p>	<p>Anti-platelet</p>	<p>Authority required (Streamlined) listing for the prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events, and the prevention of myocardial infarction or unstable angina in patients who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis with clopidogrel (as hydrogen sulfate). The equi-effective doses are 75 mg clopidogrel (as besilate) and 75 mg clopidogrel (as hydrogen sulfate).</p>
<p>Docetaxel, solution concentrate for IV infusion, 20 mg in 2 mL, 80 mg in 8 mL, Docetaxel Ebewe 20 mg®, Docetaxel Ebewe 80 mg®</p> <p>InterPharma Pty Ltd</p> <p>Minor submission (out of session)</p>	<p>Cancer treatment</p>	<p>List a new presentation of docetaxel.</p>	<p>The PBAC recommended the listing of a new ready-to-use solution presentation of docetaxel with the same price, restriction and maximum quantities as the currently PBS listed formulation of docetaxel.</p>

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<p>Eletriptan hydrobromide, tablet, 40 mg (base), 80 mg (base), Relpax®</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	<p>Treat migraine attack</p>	<p>Authority required (streamlined) listing for the treatment of migraine attacks in patients who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis with sumatriptan. The equivalent doses are eletriptan 40 mg and sumatriptan 50 mg.</p>
<p>Esomeprazole magnesium trihydrate, tablet, 20 mg, 40 mg, Nexium®</p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>	<p>Acid related disorders, such as gastro-oesophageal reflux</p>	<p>Increase the number of repeats for the 40 mg tablet, extend the restricted benefit listings of both the 20 mg and 40 mg strengths to include healing and maintenance of gastro-oesophageal reflux disease, scleroderma oesophagus and Zollinger-Ellison syndrome.</p>	<p>The PBAC recommended extending the listing of esomeprazole 20 mg tablets to include scleroderma oesophagus with a maximum quantity of 30 tablets and 5 repeats, consistent with the listings of the other PBS-subsidised proton pump inhibitors.</p> <p>The PBAC additionally recommended extending the PBS availability of esomeprazole 20 mg and 40 mg tablets to include an authority required listing for pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, with a maximum quantity of 30 x 20 mg or 40 mg tablets and 5 repeats.</p> <p>The PBAC however rejected the submission's request to amend the restriction wordings of, and increase the maximum quantity and repeats available for, esomeprazole for the healing of, and maintenance of healed, gastro-oesophageal reflux disease, on the grounds that the current wordings, maximum quantities and repeats are consistent with the treatment regimens included in the Australian approved esomeprazole product information.</p>

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<p>Ganirelix, solution for injection, 250 micrograms in 0.5 mL (as acetate), single use pre-filled syringe, Orgalutran®</p> <p>Schering-Plough Pty Ltd</p> <p>Minor submission</p>	<p>Fertility drug</p>	<p>Re-submission for Section 100 (IVF GIFT Program) listing for prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.</p>	<p>The PBAC recommended listing at the same price per IVF cycle as a 2-month course of nafarelin for endometriosis plus a cost offset for a reduction in incidence of severe ovarian hyperstimulation syndrome with gonadotrophin releasing hormone (GnRH) analogue antagonists compared to GnRH analogue agonists.</p>
<p>Glucose indicator - blood, electrode strips, 50, CareSens N®</p> <p>Life Bioscience Pty Ltd</p> <p>Minor submission (Out of session)</p>	<p>Diabetes</p>	<p>List a new test strip for blood glucose monitoring.</p>	<p>The PBAC recommended the listing of an additional brand of test strips, at the same price as the currently listed test strips.</p>
<p>Glucose indicator - blood, electrode strips, 50, WaveSense Jazz®</p> <p>HealthSense Products Pty Ltd</p> <p>Minor submission (Out of session)</p>	<p>Diabetes</p>	<p>List a new test strip for blood glucose monitoring.</p>	<p>The PBAC recommended the listing of an additional brand of test strips, at the same price as the currently listed test strips.</p>
<p>Golimumab, injection 50 mg in 0.5 mL, pre-filled syringe, single use pre-filled pen, Simponi®</p> <p>Schering-Plough Pty Ltd</p> <p>Major submission</p>	<p>Monoclonal antibody for use in ankylosing spondylitis and other chronic inflammatory diseases</p>	<p>Authority required listing for the treatment of adult patients with active ankylosing spondylitis who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis with etanercept. The equi-effective doses are golimumab 50 mg every 4 weeks and etanercept 50 mg weekly.</p>

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<p>Golimumab, injection 50 mg in 0.5 mL, pre-filled syringe, single use pre-filled pen, Simponi®</p> <p>Schering-Plough Pty Ltd</p> <p>Major submission</p>	<p>Monoclonal antibody for use in psoriatic arthritis and other chronic inflammatory diseases</p>	<p>Authority required listing for the treatment of adult patients with severe active psoriatic arthritis who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis with adalimumab and etanercept. The equi-effective doses are golimumab 50 mg every 4 weeks, adalimumab 40 mg every 2 weeks and 50 mg etanercept weekly.</p>
<p>Golimumab, injection 50 mg in 0.5 mL, pre-filled syringe, single use pre-filled pen, Simponi®</p> <p>Schering-Plough Pty Ltd</p> <p>Major submission</p>	<p>Monoclonal antibody for use in rheumatoid arthritis and other chronic inflammatory diseases</p>	<p>Authority required listing for the treatment of adult patients with severe active rheumatoid arthritis who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis with adalimumab and etanercept. The equi-effective doses are golimumab 50 mg every 4 weeks, adalimumab 40 mg every 2 weeks and 50 mg etanercept weekly.</p>
<p>High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate, powder 300 g, KetoCal®</p> <p>Nutricia Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>List an unflavoured version of the current product.</p>	<p>The PBAC recommended that this unflavoured product be made available on the PBS under the same circumstances as the existing KetoCal product.</p>
<p>Infliximab, powder for IV infusion, 100 mg, Remicade®</p> <p>Schering-Plough Pty Ltd</p> <p>Major submission</p>	<p>Monoclonal antibody for use in Crohn disease and other chronic inflammatory disease</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for the treatment of fistulising Crohn disease in patients who meet certain criteria.</p>	<p>The PBAC recommended listing on the basis of a high, but acceptable, cost effectiveness ratio, in the context of a serious medical condition that has a large impact on the quality of life of often otherwise healthy younger patients.</p>

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<p>Inactivated influenza (surface antigen) vaccine, injection in pre-filled syringe, Fluvirin®</p> <p>Novartis Vaccines and Diagnostics Pty Ltd</p> <p>Minor submission</p>	<p>Vaccine for influenza</p>	<p>Request the PBAC recommend that Fluvirin be designated as a vaccine pursuant to Section 9B (7) of the National Health Act 1953 to allow the sponsor to participate in future national tenders for supply via the National Immunisation Program (NIP).</p>	<p>Recommended.</p>
<p>Interferon beta-1a (rch), solution for injection, 132 micrograms in 1.5 mL multi-dose cartridge, Rebif 44®</p> <p>Merck Serono Australia Pty Ltd</p> <p>Minor submission (Out of session)</p>	<p>Multiple sclerosis</p>	<p>List a new multi-dose cartridge.</p>	<p>The PBAC recommended the listing of a new multi-dose cartridge presentation of interferon beta-1a for relapsing-remitting multiple sclerosis, at the same price and with the same restriction as the existing PBS listed product Rebif 44®. The PBAC noted that the sponsor stated it will provide the required electromechanical autoinjector and consumables to patients at no cost.</p>
<p>Levetiracetam, tablet, 250 mg, 500 mg, 1 g; oral solution 100 mg per mL, 300 mL, Keppra®</p> <p>UCB Australia Pty Ltd</p> <p>Minor submission (Out of session)</p>	<p>Epilepsy</p>	<p>Requests a change to an Authority required (Streamlined) listing.</p>	<p>The PBAC recommended to change the current Authority required listing to an Authority required (STREAMLINED) listing for levetiracetam on the basis of the removal of the Special Patient Contribution from the tablets by the sponsor.</p>

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<p>Levodopa with carbidopa and entacapone, tablet, 75-18.75-200 mg, 125-31.25-200 mg, Stalevo®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Minor submission (Out of session)</p>	<p>Parkinson disease</p>	<p>List 2 new strengths.</p>	<p>The PBAC recommended the listing of two new strengths of levodopa with carbidopa and entacapone, in accordance with the combination guidelines, on a cost-minimisation basis compared with the equivalent doses of the constituent components.</p>
<p>Macrogol 3350, powder for solution, 510 g, OsmoLax®</p> <p>Key Pharmaceuticals Pty Ltd</p> <p>Minor submission</p>	<p>Constipation</p>	<p>List a new form of macrogol 3350 laxative in the General and Palliative Care Schedules.</p>	<p>The PBAC recommended listing on a cost minimisation basis compared with Movicol. The equivalent doses are 17 g of macrogol 3350 and one sachet of macrogol 3350, 13.125 g with electrolytes (Movicol).</p>
<p>Methylphenidate hydrochloride, capsule (modified release), 10 mg, Ritalin LA®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Minor submission</p>	<p>Attention deficit hyperactivity disorder (ADHD)</p>	<p>List a new strength.</p>	<p>The PBAC recommended listing under the same conditions as the currently listed strengths.</p>

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<p>Milk powder -synthetic, low calcium compound powder 400 g, Locasol® Milk protein with fat formula with vitamins and minerals – carbohydrate free, powder 225 g, Carbohydrate Free Mixture®</p> <p>Nutricia Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Approval sought for minor change to the existing formulation.</p>	<p>The PBAC had no objection to the change in formulation for these products.</p>
<p>Naloxone hydrochloride, injection, 0.4 mg in 1 mL, Naloxone Min-I-Jet®</p> <p>CSL Biotherapies</p> <p>Minor submission</p>	<p>Treatment of opioid overdose</p>	<p>Unrestricted listing in the General and Dental Schedules and the Doctor's Bag.</p>	<p>The PBAC recommended listing noting that the sponsor had indicated that the currently listed naloxone injection 2 mg in 5 mL will become unavailable in the near future, and considering that there is a clinical need for an injectable naloxone product to remain available on the PBS.</p>
<p>Nicotine transdermal patch releasing 15 mg per 16 hours, Nicorette® Patch</p> <p>Cancer Council Australia, Heart Foundation, Australian Council on Smoking and Health, Quit Victoria</p> <p>Major submission</p>	<p>Help stop smoking</p>	<p>Re-submission for an Authority required listing for the treatment of nicotine dependence in concessional patients or patients for whom other smoking cessation pharmacotherapies should not be prescribed because of contraindications, precautions or adverse reactions.</p>	<p>The PBAC recommended listing in the context of a public health priority area, noting that reduction of chronic disease caused by smoking is one of the key focuses of the national health taskforce on prevention. The PBAC recommended the listing of nicotine transdermal patches at the price requested in the submission on the basis of (a) non-inferior efficacy, superior safety and lower cost compared to bupropion, and (b) uncertain and possibly inferior efficacy, superior safety and lower cost compared to varenicline. The PBAC recommended that the listing of nicotine patches be limited a maximum of 12 weeks treatment in a 12 month period.</p>

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<p>Olanzapine (as benzoate), tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg Olanzapine Generichealth®</p> <p>Generic Health Pty Ltd</p> <p>Minor submission</p>	<p>Schizophrenia, bi-polar disorder</p>	<p>List a benzoate salt of olanzapine as a new generic form (interchangeable).</p>	<p>The PBAC recommended listing on a cost minimisation basis with olanzapine (base). The equi-effective doses are 2.5 mg, 5 mg, 7.5 mg and 10 mg olanzapine (as benzoate) and 2.5 mg, 5 mg, 7.5 mg and 10 mg olanzapine, respectively.</p>
<p>Oxaliplatin, powder for IV infusion, 150 mg, Oxaliplatin 150 Link®</p> <p>Fresenius Kabi Pty Ltd</p> <p>Minor submission (Out of session)</p>	<p>Cancer treatment</p>	<p>List a new strength of oxaliplatin.</p>	<p>The PBAC recommended the listing of a new strength of oxaliplatin with the same restriction as the existing 50 mg, 100 mg and 200 mg strengths listed on the PBS, on the basis of price parity with existing strengths.</p>
<p>Palonosetron hydrochloride, solution for injection vial, 250 micrograms in 5 mL, Onicit®</p> <p>Specialised Therapeutics Australia Pty Ltd</p> <p>Major submission</p>	<p>Prevent or treat nausea and vomiting following cancer chemotherapy</p>	<p>Restricted benefit listing for management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.</p>	<p>The PBAC recommended listing on a cost-minimisation basis compared with intravenous ondansetron. The PBAC considered that the equi-effective doses to be palonosetron 250 micrograms and intravenous ondansetron 12 mg.</p>
<p>Perindopril arginine with amlodipine besylate, tablet, 5 mg-5 mg, 5 mg-10 mg, 10 mg-5 mg, 10 mg-10 mg, Coveram®</p> <p>Servier Laboratories (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Hypertension</p>	<p>Restricted benefit as substitution therapy in patients who are stabilised on treatment with perindopril and amlodipine, given concurrently at the same dose level.</p>	<p>The PBAC recommended listing in accordance with the combination guidelines, on a cost-minimisation basis compared with the corresponding strengths of its constituent components, perindopril (erbumine/arginine) and amlodipine given concomitantly.</p>

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<p>Pramipexole hydrochloride, tablet, 375 microgram, 750 microgram, 1.5 mg, 3 mg, 4.5 mg, Sifrol ER®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Minor submission</p>	<p>Parkinson disease</p>	<p>List an extended release formulation.</p>	<p>The PBAC recommended listing at the same price per mg (based on the closest pack size) as pramipexole immediate release.</p>
<p>Raltegravir potassium, tablet 400 mg (base), Isentress®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>HIV infection</p>	<p>Section 100 (Highly Specialised Drugs Program) listing as first-line therapy for patients with HIV infection who meet certain criteria.</p>	<p>The PBAC recommended listing on a cost minimisation basis compared with efavirenz. The equi-effective doses are 800 mg raltegravir per day and 600 mg efavirenz per day.</p>
<p>Ritonavir, tablet, 100 mg, Norvir®</p> <p>Abbott Australasia Pty Ltd</p> <p>Minor submission</p>	<p>HIV infection</p>	<p>List a tablet form to replace the currently listed capsules.</p>	<p>The PBAC recommended listing at the same price per tablet as the currently listed ritonavir capsules.</p>
<p>Rivaroxaban, tablet 10 mg, Xarelto®</p> <p>Bayer Healthcare (Bayer Schering Pharma Pty Ltd)</p> <p>Minor submission (Out of session)</p>	<p>Prevention of blood clot formation following surgery</p>	<p>Review pack size and quantity description, specifically which pack size can be broken.</p>	<p>The PBAC recommended to change the current listings to allow the 15 tablet pack size to be broken and to place the limitation to not break the pack on the 10 tablet pack size.</p>

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<p>Romiplostim, powder for injection, 165 micrograms, 375 micrograms, 625 micrograms, (Nplate®)</p> <p>Amgen Australia Pty Ltd</p> <p>Major submission</p>	<p>Increases platelet production</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for the initial and continuing treatment of adult patients with chronic immune idiopathic thrombocytopenic purpura who meet certain criteria.</p>	<p>The PBAC recommended listing on the basis of a high but acceptable cost effectiveness ratio, in the context of a high clinical need in a small subgroup of ITP patients.</p>
<p>Rosuvastatin calcium, tablet, 5 mg (rosuvastatin), 10 mg (rosuvastatin), 20 mg (rosuvastatin), 40 mg (rosuvastatin), Crestor®</p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>	<p>Lowers blood cholesterol</p>	<p>Inclusion in the 12 month repeat prescription measure.</p>	<p>The PBAC recommended that rosuvastatin be included in the 12 month repeat prescription for chronic disease measure.</p>
<p>Saxagliptin, tablets, 2.5 mg, 5 mg, Onglyza®</p> <p>Bristol-Myers Squibb Pharmaceuticals</p> <p>Major submission</p>	<p>Lowers blood sugars</p>	<p>Authority required (Streamlined) listing for use in type 2 diabetes in combination with metformin or a sulphonylurea.</p>	<p>The PBAC recommended listing on a cost-minimisation basis with sitagliptin with the equivalent doses of saxagliptin 5 mg/day and sitagliptin 100 mg/day.</p>

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<p>Somatropin, injection, 5 mg (15 iu) in 1 mL cartridge (with preservative), 12 mg (36 iu) in 1 mL cartridge, Genotropin GoQuick®</p> <p>Pfizer Australia Pty Ltd</p> <p>Minor submission (Out of session)</p>	<p>Growth hormone</p>	<p>List a new disposable pen presentation.</p>	<p>The PBAC recommended the listing of a new presentation of somatropin 5 mg and 12 mg pens.</p>
<p>Thalidomide, capsule, 100 mg, 200 mg, Thalomid®</p> <p>Celgene Pty Ltd</p> <p>Minor submission</p>	<p>Multiple myeloma</p>	<p>Requests listing of two new higher strengths of thalidomide.</p>	<p>The PBAC recommended the listing of two new strengths of thalidomide capsules on the PBS under the same circumstances as the currently subsidised capsules.</p>
<p>Tipranavir, oral solution, 100 mg per mL, Aptivus®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Minor submission</p>	<p>HIV infection</p>	<p>List a new dosage form.</p>	<p>The PBAC recommended listing at the same price per mg of tipranavir as the capsules.</p>
<p>Tocilizumab, solution for IV infusion, 80 mg in 4 mL, 200 mg in 10 mL and 400 mg in 20 mL, Actemra®</p> <p>Roche Products Pty Ltd</p> <p>Major submission</p>	<p>Monoclonal antibody for use in rheumatoid arthritis and other chronic inflammatory diseases</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for first-line treatment in combination with methotrexate in patients with severe active rheumatoid arthritis who meet certain criteria.</p>	<p>The PBAC recommended amending the recommended restriction to allow first line use for the treatment of severe active rheumatoid arthritis whether when used as monotherapy or in combination with methotrexate.</p>

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<p>Triglycerides - medium chain and long chain with glucose polymer, sachets, 16 g, MCT Pro-Cal®</p> <p>VitaFlo Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Change maximum quantity.</p>	<p>The PBAC recommended that the item description be changed from '25 sachets' to '30 sachets' but that the maximum quantity and repeats description remain unchanged at 4 and 5 respectively.</p>
<p>Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose, sachet, 100 g, RenaStart®</p> <p>VitaFlo Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Change maximum quantity.</p>	<p>The PBAC recommended that the maximum quantity be changed from 8 to 9 following advice from the sponsor that RenaStart would be supplied in outer cartons that contain 30 sachets (i.e. thereby allowing a multiple of 30 to be supplied).</p>
<p>Valganciclovir hydrochloride, powder for oral solution, 50 mg per mL, Valcyte®</p> <p>Roche Products Pty Ltd</p> <p>Minor submission</p>	<p>Anti-viral</p>	<p>Section 100 (Highly Specialised Drugs Program) listing of a new dosage form with the same restrictions as the 450 mg tablets.</p>	<p>The PBAC recommended listing under the same circumstances as the currently subsidised tablets.</p>

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<p>Vildagliptin, tablets, 50 mg, Galvus®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Lowers blood sugars</p>	<p>Authority required (Streamlined) listing for use in type 2 diabetes in combination with metformin or a sulphonylurea.</p>	<p>The PBAC recommended listing on a cost-minimisation basis with sitagliptin. The equi-effective doses in the setting of combination usage with metformin are vildagliptin 50 mg twice daily, sitagliptin 100 mg daily, pioglitazone 30 mg daily, and rosiglitazone 8 mg daily. The equi-effective doses in the combination usage with sulphonylurea are vildagliptin 50 mg once daily, sitagliptin 100 mg daily, pioglitazone 30 mg daily, and rosiglitazone 8 mg daily.</p>
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