MARCH 2006 PBAC OUTCOMES – POSITIVE RECOMMENDATIONS

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ADALIMUMAB, prefilled syringe, 40 mg, Humira® Abbott Australasia Pty Ltd Major submission	Psoriatic arthritis, rheumatoid arthritis	Authority required listing for severe active psoriatic arthritis in patients who meet certain criteria.	The PBAC recommended listing on a cost-minimisation basis concluding that the indirect comparison showed that adalimumab is no worse than etanercept in terms of effectiveness and safety when used for the treatment of psoriatic arthritis. The equi-effective doses are adalimumab 40 mg every second week compared with etanercept 25 mg twice a week. The PBS restriction to apply to adalimumab should align as closely as possible to the recommended restriction for etanercept for the treatment of psoriatic arthritis, taking into account differences in the dosage regimens that apply. The PBAC recommended that interchangeability arrangements be implemented for all biological agents listed for the treatment of this patient group. The restriction will be posted on the website when finalised.
ADRENALINE, IM injection auto-injector, 150 micrograms & 300 micrograms, EpiPen® & EpiPen Jr® CSL Pty Ltd Minor submission	Emergency treatment of acute allergic reactions with anaphylaxis,	Change the current listing by the addition of the wording as follows: Authority required Initial supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been discharged from hospital or an emergency department after treatment	The PBAC recommended a change to the current authority required listing as requested in recognition of current access issues for Epipen, to allow for situations where a patient is admitted to hospital for the treatment of anaphylaxis. The Committee noted concerns expressed by specialists about possible risks associated with such a move and thus requested that the National Prescribing

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		with adrenaline for acute allergic reaction with anaphylaxis.	Service produce educational material to inform prescribers of the change, and that the DUSC continue to monitor usage.
ANASTROZOLE, tablet, 1 mg, Arimidex®, AstraZenca Pty Ltd Minor submission	Treatment of hormone-dependent breast cancer in post-menopausal women.	Add the following NOTE to the current restriction NOTE: This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.	The PBAC recommended the addition of the NOTE to the current restriction to clarify its intent that the duration of hormonal therapy for the treatment of early stage breast cancer should be limited to 5 years.
APREPITANT, capsule, 125 mg (1) and 80 mg (2), Emend®. Merck Sharp & Dohme (Australia) Pty Ltd Major submission	Treatment for nausea and vomiting associated with chemotherapy	Add to the listing the following: Patients undergoing treatment for breast cancer with a chemotherapy regimen containing either an anthracycline (i.e doxorubicin or epirubicin) plus cyclophosphamide (i.e AC, EC, FEC, or FAC) or cyclophosphamide plus methotrexate plus 5-fluorouracil (ie. CMF). .	The PBAC recommended listing on the basis of acceptable cost-effectiveness as compared to placebo for the management of nausea and vomiting associated with cytotoxic chemotherapy, comprising cyclophosphamide and an anthracycline, being used to treat breast cancer, only. It was noted that the CMF combination regimen contributes little to the evidentiary basis in the submission for including this combination in any PBS restriction. The PBAC therefore recommended that this combination be excluded from the restriction.
AMINO ACID FORMULA WITH VITAMINS and MINERALS without PHENYLALANINE, 125 mL pouch, Lophlex LQ®,	Food for special medical purpose	Different dose form of an existing PBS listing.	The PBAC had no objection to the Secretariat listing of this nutritional product based on the advice of the advice of the Nutritional Products Working Party.

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Scientific Hospital Supplies International Ltd Minor submission			
ALENDRONATE SODIUM with VITAMIN D3, tablet, 70 mg and 2800 IU, Fosamax® Plus. Merck Sharp & Dohme (Australia) Pty Ltd Major Submission	Osteoporosis	Authority required for treatment of established osteoporosis in patients with fracture due to minimal trauma, in patients who require a supplemental intake of vitamin D.	The PBAC recommended listing on a cost-minimisation basis with the alendronate sodium 70 mg formulation, on a mg per mg basis of the alendronate component, with the same restriction as for alendronate sodium 70 mg. The PBAC noted that alendronate plus vitamin D provides access to a combination product for patients with established osteoporosis who may require vitamin D supplementation. However, the PBAC considered that 400 iu colecalciferol per day, would not be adequate for those patients who are genuinely vitamin D deficient.
CANDESARTAN CILEXETIL, tablet, 32 mg, Atacand®, AstraZeneca Pty Ltd. Minor submission	Angiotensin II receptor antagonist used to treat hypertension and heart failure	The company requested listing of a new strength tablet, 32 mg.	The PBAC had no objection to the Secretariat decision to add a new strength to the current unrestricted benefit listing.
DARBEPOETIN ALFA, injection 40 micrograms in 0.4 mL pre-filled pen, injection 60 micrograms in 0.3 mL pre-filled pen, injection 80 micrograms in 0.4 mL pre-filled pen, injection 100 micrograms in 0.5 mL	Treatment of anaemia requiring transfusion.	Listing of an additional auto-injector device for currently listed strengths.	The PBAC had no objection to the Secretariat listing of auto-injector devices for sub-cutaneous use for selected strengths of currently listed Aranesp® pre-filled syringes. The PBAC noted the sponsor's request to maintain all existing strengths of the pre-filled

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
pre-filled pen, injection 150 micrograms in 0.3 mL pre-filled pen, Aranesp® SureClick. Minor submission			syringes on the PBS.
DIPHTHERIA AND TETANUS VACCINE, ADSORBED (ADT), Maximum quantity in Doctors Bag Minor Submission	Vaccine for diphtheria and Tetanus	Unrestricted (general list) Emergency Drug (Doctors Bag) supplies Request for increased quantities of diphtheria and tetanus vaccine	Following the discontinuation of the manufacture of tetanus vaccine, the PBAC agreed to the request of the Australian Medical Association and the Royal Australian College of General Practitioners to increase the maximum quantity of ADT available as a Doctor's Bag item from 15 to 20.
DOCETAXEL, vial, 20 mg, 80 mg, Taxotere®. Sanofi-Aventis Australia Pty Ltd Major submission	Breast cancer	Adjuvant treatment of operable node positive, oestrogen receptor positive breast cancer in combination with an anthracycline and cyclophosphamide.	The PBAC recommended listing on the basis of acceptable cost-effectiveness comparing docetaxel + doxorubicin + cyclophosphamide (TAC) with fluorouracil + doxorubicin + cyclophosphamide (FAC) for the adjuvant treatment of node-positive breast cancer, irrespective of oestrogen receptor (ER) status.
EPOPROSTENOL SODIUM, vial, 500 microgram, 1.5 mg, Flolan®. GlaxoSmithKline Australia Pty Ltd Major submission	Pulmonary hypertension	Section 100 listing for the treatment of certain patients with severe (Class III or IV) primary pulmonary hypertension.	The PBAC recommended listing on a cost-minimisation basis concluding that based on the indirect comparison, epoprostenol is therapeutically no worse than bosentan. The equi-effective doses are epoprostenol, commencing at an average dose of 11.9 ng/kg per min over the first three months of treatment and escalating linearly in steps to an average

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			dose of 27.2 ng/kg/min at 3 years, and bosentan 125 mg twice a day. The recommended listing is to be consistent with the TGA approved indication, and will allow for interchangeability with bosentan, iloprost and treprostinil. The restriction will be posted on the website when finalised.
EPOETIN BETA, injection pre-filled syringe, 4,000 IU/0.3mL, 6,000 IU/ 0.3 mL, 20,000 IU/ 0.6 mL, 30,000 IU/ 0.6 mL, Neorecormon®, Roche Pharmaceuticals. Minor submission	Treatment of anaemia in patients with renal disease,	Add four new strengths	The PBAC had no objection to the Secretariat decision to add four new strengths to those recommended at the November 2005 PBAC.
ETANERCEPT, vial, 25 mg, 50 mg, Enbrel®. Wyeth Australia Pty Ltd Major submission	Psoriasis	Treatment by a dermatologist of certain patients aged 18 years or older with severe chronic plaque psoriasis where lesions have been present for at least 6 months and have failed to achieve an adequate response to specified therapies.	The PBAC recommended listing on a cost-minimisation basis concluding that, based on an indirect comparison, etanercept was no worse than efalizumab for the treatment of severe refractory chronic plaque psoriasis. The equi-effective doses are etanercept 25 mg twice per week on a 12 week cyclical basis to provide for a total of 24 weeks of active etanercept treatment over 48 weeks and efalizumab 1 mg/kg/week for a total of 48 weeks. The PBAC recommended that interchangeability arrangements be implemented for all biological agents listed for the treatment of this patient group.

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			The restriction will be posted on the website when finalised.
FAMCICLOVIR, tablet, 500 mg, Famvir®, Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Antiviral treatment	The company requested listing of an additional strength to the 125 mg and 250 mg tablets.	The PBAC had no objection to these Secretariat listings to allow for treatment of immunocompromised patients, with herpes zoster or recurrent genital herpes.
FENTANYL, transdermal patch, 12 microgram per hr, 25 microgram per hr, 50 microgram per hour, 75 microgram per hour, 100 microgram per hour, Durogesic®. Janssen-Cilag Pty Ltd Major submission	Narcotic analgesic	Change listing to include chronic severe disabling pain not responding to non-narcotic analgesics.	The PBAC recommended listing on a cost-minimisation basis for patients with non-cancer related pain, concluding that transdermal fentanyl is no worse than oral sustained-release morphine (OSRM) in terms of effectiveness and toxicity for this patient group. The equi-effective doses are 1 mg fentanyl being equivalent to 98.8 mg morphine across the two indications of cancer and non-cancer pain. The PBAC considered it appropriate that a NOTE be included in the PBS listing, as follows: “Durogesic is not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 microgram per hour).”
FENTANYL transdermal patch,	Narcotic analgesic	Listing of a new lower strength	The PBAC had no objection to the Secretariat

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12 microgram per hr, 25 microgram per hr, 50 microgram per hour, 75 microgram per hour, 100 microgram per hour, Durogesic®, Janssen-Cilag. Minor Submission		12 microgram per hour patch and listing of the reformulation of fentanyl transdermal patches	listing of the reformulation of fentanyl transdermal patches and addition of a lower strength 12 microgram per hour patch.
FERROUS FUMARATE with FOLIC ACID, tablet, 310 mg – 300 micrograms, Ferro-F-Tab® , AFT Pharmaceuticals Pty Ltd Minor Submission	Iron/folic acid supplement	Unrestricted listing	The PBAC recommended the listing in view of the removal of FGF tablets from the PBS on 1 April 2005. The Committee considered it to be appropriate that such a product be available on the PBS to cater for concessional status patients with conditions requiring iron and folic acid supplementation. It was also noted that there was a need for this product by Indigenous Australians.
GLUCOSE INDICATOR – BLOOD, electrode strips, 50, FreeStyle Papillon®, MediSense Products. Minor submission	Testing strips for use by diabetics	Listing of test strips for a new self-monitoring blood glucose system.	The PBAC had no objection to the Secretariat listing of test strips for a new self-monitoring blood glucose system.
INFLIXIMAB, powder for injection 100 mg, Remicade®. Schering-Plough Pty Ltd Major submission	Psoriatic arthritis	Section 100 Authority required for management of certain patients with severe active psoriatic arthritis who meet certain criteria.	The PBAC recommended listing on a cost-minimisation basis concluding that the indirect comparison showed that infliximab is no worse than etanercept in terms of effectiveness and

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
			safety when used for the treatment of psoriatic arthritis. The equi-effective doses are infliximab 5 mg/kg given for 7.25 infusions in total, compared with etanercept 25 mg twice a week, given for one year. The PBAC recommended that interchangeability arrangements be implemented for all biological agents listed for the treatment of this patient group. The restriction will be posted on the website when finalised.
INTERFERON ALFA-2a, injection, single dose pre-filled syringe, all strengths, Roferon-A®, Roche Products Pty Ltd Minor submission	Treatment for Hepatitis C	Remove from the PBS for the treatment of hepatitis C	The PBAC recommended, based on advice received from the Australian Liver Association and support from the sponsor, that non-pegylated interferon products be removed from the PBS for the treatment hepatitis C, because prescribers have transferred to the pegylated forms of interferon in the treatment of hepatitis C.
INTERFERON ALFA-2b, injection, all strengths, all presentations, Intron-A®, Schering-Plough Pty Ltd Minor submission	Treatment for Hepatitis C	Remove from the PBS for the treatment of hepatitis C.	The PBAC recommended, based on advice received from the Australian Liver Association and support from the sponsor, that non-pegylated interferon products be removed from the PBS for the treatment hepatitis C, because prescribers have transferred to the pegylated forms of interferon in the treatment of hepatitis C.

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LOPINAVIR with RITONAVIR, tablet 200 mg – 50 mg, Kaletra®, Abbott Australasia Pty Ltd. Minor submission	Antiretroviral treatment	Listing of a new form and strength of Kaletra®	The PBAC had no objection to the Secretariat listing of a new form and strength of Kaletra® with a pack size of 120, as a replacement for the currently listed soft capsules (133.3 mg- 33.3 mg).
MELOXICAM, capsule 7.5 mg, capsule 15 mg, Mobic®, Boehringer Ingelheim. Minor submission	Non steroidal anti-inflammatory agent	Listing of new dosage forms as a restricted benefit listing for the symptomatic treatment of osteoarthritis.	The PBAC had no objection to the Secretariat listing of new capsular dosage forms in addition to the currently listed tablets.
MIRTAZAPINE, tablet, 45 mg, Avanza®, Organon (Australia) Pty Ltd. Minor submission	Major depressive disorders	List an additional strength tablet (45 mg) with the same indication, maximum quantity and repeats as currently listed mirtazapine preparations.	The PBAC had no objection to the Secretariat listing of an additional strength tablet (45 mg) with the same indication, maximum quantity and repeats as current mirtazapine preparations.
MOXONIDINE, tablet, 200 micrograms, 400 micrograms, Physiotens®. Solvay Pharmaceuticals Major submission	Hypertension	Restricted benefit for the treatment of hypertension.	The PBAC recommended listing on a cost-minimisation basis, concluding that moxonidine is no worse than clonidine as add-on therapy for the treatment of hypertension, and overall, appears to be less toxic. The equi-effective doses are moxonidine 0.380 mg per day and clonidine 0.357 mg per day, based on the average dose at steady state across the two key trials included in the submission. The PBAC considered it appropriate to initially

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			list moxonidine as a restricted benefit for "Hypertension in patients receiving concurrent antihypertensive therapy".
PEGFILGRASTIM, injection 6 mg in 0.6 mL single use pre-filled pen, Neulasta® SureClick. Amgen Australia Pty Ltd Minor submission	Treatment of neutropenia caused by chemotherapy	Listing of an additional auto-injector device for currently listed strengths. For sub-cutaneous use only.	The PBAC had no objection to the Secretariat listing of an auto-injector device for Neulasta® in addition to the currently listed pre-filled syringe. The listing is to be identical to the currently listed pre-filled syringe.
PERINDOPRIL ARGININE, tablet, 2.5 mg, 5 mg, 10 mg, Coversyl®, Servier Pty Ltd. Minor submission	Treatment for hypertension and other cardiovascular disorders	Listing of a new salt of perindopril.	The PBAC had no objection to the Secretariat listing of the change of perindopril salt from erbumine to arginine. The PBAC noted the sponsor's advice that it will be implementing a communication strategy to inform prescribers of the change.
PACLITAXEL, vial, 30 mg in 5 mL, 100 mg in 16.7 mL, 150 mg in 25 mL, 300 mg in 50 mL, Anzatax®. Maynepharma Pty Ltd Major submission	Breast cancer, ovarian cancer and lung cancer	Change listing of authority required restriction to include adjuvant treatment of node-positive, breast cancer administered sequentially to doxorubicin hydrochloride and cyclophosphamide.	The PBAC recommended extension to the current listing as requested in the submission to allow for the adjuvant treatment of node positive breast cancer irrespective of oestrogen receptor status, on a cost-effectiveness basis as compared to no sequential therapy following an anthracycline and cyclophosphamide.
PEGINTERFERON ALFA-2a, injections, single use pre-filled	Treatment of Hepatitis C	Change to listing to be consistent with the listing for peginterferon alfa-2a with	The PBAC recommended changes to the current restriction for peginterferon

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syringe, 135 micrograms and 180 micrograms, Pegasys® Minor submission		ribavirin, as follows: Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa therapy or peginterferon alfa treatment for the treatment of hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks.	alfa-2a to improve consistency between the peginterferon products with and without ribavirin for the treatment of hepatitis C. These changes were considered necessary in light of the PBAC recommendations to extend the PBS listing for peginterferon alfa-2a (Pegasys®) to include the treatment of hepatitis B; to remove the requirement for an elevated ALT level from the peginterferon with ribavirin combinations; and to remove the requirement for liver biopsy for access to all peginterferon products for the treatment of hepatitis C. These changes concord with input received from the sponsor and the Australian Liver Association.
PEGINTERFERON ALFA-2b, single use injection pens containing powder for injection in vials of 50, 80, 100, 120 and 150 micrograms, PEG-Intron Redipen® Minor submission	Treatment of Hepatitis C	Change to listing to be consistent with the listing for peginterferon alfa-2b with ribavirin, as follows: Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa therapy or peginterferon alfa treatment for the treatment of hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C	The PBAC recommended changes to the current restriction for peginterferon alfa-2b to improve consistency between the peginterferon products with and without ribavirin for the treatment of hepatitis C. These changes were considered necessary in light of the PBAC recommendations to extend the PBS listing for peginterferon alfa-2a (Pegasys®) to include the treatment of hepatitis B; to remove the requirement for an elevated ALT level from the peginterferon with ribavirin combinations; and to remove the requirement for liver biopsy for access to all peginterferon

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
		infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks.	products for the treatment of hepatitis C. These changes concord with input received from the sponsor and the Australian Liver Association.
PIOGLITAZONE tablet 15 mg, 30 mg & 45 mg, Actos®, Eli Lilly Australia Pty Ltd Minor submission	Oral anti-diabetic agent	Request to simplify restriction wording as follows: Add a description of type of treatment as a header; Remove the requirements to provide a HbA1c result greater than 7%; Remove the mention of diet and exercise; Replace 'maximally tolerated doses' with 'optimal doses'; and Replace 'contraindicated or not tolerated' with 'inappropriate' to minimise the number of words in the indication and to combine the concept of contraindicated or not tolerated. Review restriction for patients in whom it is not possible to provide glycosolated haemoglobin (HbA1c), eg patients with thalassemia minor.	The PBAC recommended changing the restrictions for pioglitazone to simplify where possible the current PBS listing. The PBAC agreed that the addition of headings would better identify eligible patient groups for prescribers. The PBAC did not endorse any removal of the requirement for HbA1c levels to be above 7%, and recommended maintaining the requirement for the date of testing to be provided at the time of authority application for initiation of treatment, on the basis that this was pivotal to the initial recommendation to listing the glitazones on the PBS, and their positioning as third line therapy. The PBAC further considered that this requirement was necessary in order to demonstrate that patients were not responding to treatment with oral hypoglycaemic agents or insulin at the time of application. The PBAC also recommended that the restriction be modified to allow for patients for whom it was not possible to provide a HbA1c level due to conditions that shorten red blood

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			cell survival, to have results of blood glucose monitoring provided instead. Link to pioglitazone restriction.
RIBAVIRIN and PEGINTERFERON ALFA-2a, injections, pre-filled syringe, 135 micrograms and 180 micrograms and capsules 200 mg, (all pack sizes), Pegasys RBV® Roche Products Minor submission	Treatment of Hepatitis C	Change to listing to include the words: Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment **for the treatment of hepatitis C** and …	The PBAC recommended this change to the current restriction for peginterferon alfa-2a in combination with ribavirin, as requested. This change was considered necessary in light of the November 2005 PBAC recommendation to extend the PBS listing for peginterferon alfa-2a (Pegasys®) to include the treatment of hepatitis B and as a result of advice from the sponsor and the Australian Liver Association.
RIBAVIRIN and PEGINTERFERON ALFA-2b, single use injection pens containing powder for injection in vials of 50, 80, 100, 120 and 150 micrograms and capsules 200 mg, (all pack sizes), Pegatron® Schering Plough Pty Ltd Minor submission	Treatment of Hepatitis C	Change to listing to include the words Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment **for the treatment of hepatitis C** and ….	The PBAC recommended this change to the current restriction for peginterferon alfa-2b in combination with ribavirin, as requested. This change was considered necessary in light of the November 2005 PBAC recommendation to extend the PBS listing for peginterferon alfa-2a (Pegasys®) to include the treatment of hepatitis B and as a result of advice from the sponsor and the Australian Liver Association.
RISPERIDONE, powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe, powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent	Schizophrenia	Listing of new pack with a needle-free vial access device.	The PBAC had no objection to the Secretariat listing of a new pack which enables a safer and faster reconstitution process.

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in pre-filled syringe, powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe, Risperdal® Consta®, Janssen-Cilag Pty Ltd Minor submission			
RITUXIMAB, solution for I.V. infusion, 100 mg in 10 mL, 500 mg in 50 mL, Mabthera®, Roche Products Pty Ltd Major submission	Non-Hodgkin's lymphoma	Extend the current indication to include the treatment of previously untreated patients with CD20 positive, stage III/IV, follicular B-cell non-Hodgkins's lymphoma, in combination with chemotherapy.	The PBAC recommended extension to the current listing on a cost-effectiveness basis as compared to placebo when used in combination with chemotherapy, noting that points raised by the PBAC in the previous submission, had been addressed adequately in the current submission.
ROSIGLITAZONE tablet, 4 mg & 8 mg, Avandia®. GlaxoSmithKline Australia Pty Ltd Minor submission	Oral anti-diabetic agent	Request to simplify restriction wording as follows: Add a description of type of treatment as a header; Remove the requirements to provide a HbA1c result greater than 7%; Remove the mention of diet and exercise; Replace 'maximally tolerated doses' with 'optimal doses'; and Replace 'contraindicated or not tolerated' with 'inappropriate' to minimise the number of words in the indication and to combine the concept of contraindicated or not tolerated.	The PBAC recommended changing the restrictions for rosiglitazone to simplify where possible the current PBS listing. The PBAC agreed that the addition of headings would better identify eligible patient groups for prescribers. The PBAC did not endorse any removal of the requirement for HbA1c levels to be above 7%, and recommended maintaining the requirement for the date of testing to be provided at the time of authority application for initiation of treatment, on the basis that this was pivotal to the initial recommendation to listing the glitazones on the PBS, and their positioning as third line therapy. The PBAC further considered that this requirement was

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		Review restriction for patients in whom it is not possible to provide glycosolated haemoglobin (HbA1c), eg patients with thalassemia minor.	necessary in order to demonstrate that patients were not responding to treatment with oral hypoglycaemic agents or insulin at the time of application. The PBAC also recommended that the restriction be modified to allow for patients for whom it was not possible to provide a HbA1c level due to conditions that shorten red blood cell survival, to have results of blood glucose monitoring provided instead. Link to rosiglitazone restriction.
TOPIRAMATE, capsule, 15 mg, 25 mg, 50 mg Topamax Sprinkle® Janssen-Cilag Pty Ltd Minor submission	Anti-epileptic	Amend restriction	The PBAC agreed to amend the authority required restriction to "treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate." The PBAC advised that a small price advantage over the other anti-epileptic drugs in the reference pricing group was acceptable for the capsule (sprinkle) formulation of topiramate on the grounds that it provides a formulation for patients unable to take a solid dose form.
VINORELBINE, capsule, 20 mg, 30 mg, Navelbine®. Pierre Fabre Medicament Australia Pty Ltd	Lung cancer	Authority required for treatment of locally advanced or metastatic non-small cell lung cancer.	The PBAC recommended listing on a cost-minimisation basis, concluding that orally administered vinorelbine is no worse than intravenously administered vinorelbine in terms

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Major submission			of effectiveness and toxicity. The equi-effective doses are one 3-week cycle at 60mg/m2 and two 3-week cycles at 80mg/m2 for oral vinorelbine and three 3-week cycles at 30mg/m2 for intravenous vinorelbine.
VACCINES:			
PERTUSSIS VACCINE ACELLULAR with DIPHTHERIA and TETANUS TOXOIDS, ADSORBED, injection, 0.5 mL, Adacel®, Sanofi Pasteur Pty Ltd Major submission	Vaccine for Pertussis, Diphtheria and Tetanus	National Immunisation Program For adolescents aged at least 10 years but less than 18 years for active immunisation against tetanus, diphtheria and pertussis as a booster following primary immunisation	The PBAC recommended funding under the National Immunisation Program on a cost-minimisation basis, concluding that a single booster dose of Adacel is as effective as a single booster dose of Boostrix in terms of impact on pertussis, diphtheria and tetanus. The equi-effective doses are 0.5 mL of Adacel and 0.5 mL of Boostrix.
MEDICINES FOR INDIGENOUS AUSTRALIANS:			
THIAMINE, tablet, 100 mg, Betamin® Sanofi-Aventis Pty Ltd Minor submission	Vitamin B1 supplement	Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person.	The PBAC recommended listing as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians” for this patient group.
MEDICINES FOR INDIGENOUS AUSTRALIANS TOPICAL ANTIFUNGAL PREPARATIONS:			

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BIFONAZOLE, cream, 10 mg per g (1%), 15 g, Mycospor®, Bayer HealthCare Minor submission	Topical antifungal	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	The PBAC had no objection to the PBS listing of this product as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians”.
CLOTRIMAZOLE, cream, 10mg per g (1%), 20 g, Clonea®, Alphapharm Pty Ltd Minor submission	Topical antifungal	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	The PBAC had no objection to the PBS listing of this product as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians”.
CLOTRIMAZOLE, cream, 10 mg per g (1%), 20 g & 50 g, Clozole®, Cipla Genpharm Australia Pty Ltd Minor submission	Topical antifungal	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	The PBAC had no objection to the PBS listing of this product as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians”.
CLOTRIMAZOLE, lotion, 10 mg per mL (1%), 20 mL, Canesten®, Bayer HealthCare Minor submission	Topical antifungal	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	The PBAC had no objection to the PBS listing of this product as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians”.
NYSTATIN, cream, 100,000 units	Topical antifungal	Treatment of a fungal or a yeast	The PBAC had no objection to the PBS listing

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per g, 15 g, Mycostatin®, Bristol-Myers Squibb Pharmaceuticals Minor submission		infection in an Aboriginal or a Torres Strait Islander person.	of this product as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians”.
KETOCONAZOLE, cream, 20 mg per g (2%), 30 g; Shampoo, 10 mg per g (1%) 100 mL & 20 mg per g (2%) 60 mL; Nizoral®, Janssen-Cilag Minor submission	Topical antifungal	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	The PBAC had no objection to the PBS listing of this product as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians”.
MICONAZOLE NITRATE, Cream, 20 mg per g (2%), 15 g, 30 g & 70 g; Powder , 20 mg per g (2%), 30 g; Lotion, 20 mg per mL (2%), 30 g; Tincture 20 mg per mL (2%), 30 mL; Daktarin®, Janssen-Cilag Pty Ltd Minor submission	Topical antifungal	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	The PBAC had no objection to the PBS listing of this product as an authority required benefit under the arrangements made for the 2004-05 Budget measure “Improving the capacity of the PBS to meet the needs of Indigenous Australians”.
PALLIATIVE CARE LISTINGS			
BENZYDAMINE HYDROCHLORIDE Mouth and throat rinse 22.5 mg per 15 mL, 500 mL, Difflam®, 3M Pharmaceuticals Australia Pty Ltd.	Painful conditions of the mouth	Authority required listing for: Initial supply (for up to 4 months) for palliative care patients where a painful mouth is a problem; Continuing supply for palliative care	The PBAC agreed to a request from the Palliative Care Medications Working Group that benzydamine be included in the Palliative Care Schedule to allow access for palliative care patients who were unable to access the

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Minor submission		patients where a painful mouth is a problem and where consultation with a palliative care specialist or service has occurred. Continuing supply for palliative care patients where a painful mouth is a problem.	medication via the current restricted benefit listing.
LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, Actilax®, Alphapharm Pty Limited; Genlac®, Arrow Pharmaceuticals Limited; GenRx Lactulose®, GenRx Pty Ltd; Lac-Dol®; Douglas Pharmaceuticals Australia Ltd; Lactocur®, Hexal Australia Pty Ltd; Duphalac®, Solvay Pharmaceuticals. Minor submission	Constipation	Authority required listing for: Initial supply (for up to 4 months) for palliative care patients where constipation is a problem; Continuing supply for palliative care patients where constipation is a problem and where consultation with a palliative care specialist or service has occurred. Continuing supply for palliative care patients where constipation is a problem.	The PBAC agreed to a request from the Palliative Care Medications Working Group that lactulose mixture be included in the Palliative Care Schedule to allow access for palliative care patients who were unable to access the medication via the current restricted benefit listing.
MACROGOL 3350 Sachets containing powder for solution 13.125 g with electrolytes, 30, Movicol®, Norgine Pty Limited. Minor Submission	Constipation	Authority required listing for: Initial supply (for up to 4 months) for palliative care patients where constipation is a problem; Continuing supply for palliative care patients where constipation is a problem and where consultation with a palliative care specialist or service has occurred. Continuing supply for palliative care patients where constipation is a	The PBAC agreed to a request from the Palliative Care Medications Working Group that macrogol sachets be included in the Palliative Care Schedule to allow access for palliative care patients who were unable to access the medication via the current restricted benefit listing.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
		problem.	
PARACETAMOL Tablet 665 mg (modified release);Duatrol SR®, Menley and James, (Division of GlaxoSmithKline Australia); Panadol Osteo®, GlaxoSmithKline Consumer Healthcare Minor submission	Analgesic	Increase maximum quantity	The PBAC had no objection to changing the current modified release paracetamol Palliative Care Listing by increasing the maximum quantity from 96 to 192, and the maximum repeats from 3 to 5, to bring the listing into line with the standard section 85 listing.
NAPROXEN, oral suspension, 125 mg per 5mL, Naprosyn®, Roche Products Pty Ltd. Minor submission	Non-steroidal anti-inflammatory agent.	Authority required listing for: Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent. Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent. Continuing supply for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent.	The PBAC agreed to a request from the Palliative Care Medications Working Group that naproxen suspension be included in the Palliative Care Schedule to allow access for palliative care patients who were unable to access this medication.
MORPHINE SULFATE, tablet 10 mg	Narcotic analgesic	Authority required listing for:	The PBAC agreed to a request from the

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
and 20 mg, Sevredol®, Mundipharma Pty Ltd Minor submission		Initial supply (for up to 3 months) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics. Continuing supply (for up to 3 months) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics and where consultation with a palliative care specialist or service has occurred. Continuing supply (for up to one month) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics.	Palliative Care Medications Working Group that morphine sulfate tablets be included in the Palliative Care Schedule to allow access for palliative care patients. A change to the explanatory notes at the front of the Palliative Care Schedule will need to be made, advising prescribers that prescribing of natural opium alkaloids must be in accordance with standard section 85 requirements and State and Territory legislation.
MORPHINE SULFATE, tablet, 200 mg (controlled release), MS Contin®, Mundipharma Pty Ltd Minor submission	Narcotic analgesic	Authority required listing for: Initial supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics. Continuing supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics and where consultation with a palliative care specialist or service has occurred. Continuing supply (for up to one month) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics;	The PBAC agreed to a request from the Palliative Care Medications Working Group that morphine sulfate controlled release tablets be included in the Palliative Care Schedule to allow access for palliative care patients. A change to the explanatory notes at the front of the Palliative Care Schedule will need to be made, to provide advice to prescribers regarding the prescribing of natural opium alkaloids which must be in accordance with standard section 85 requirements and State and Territory legislation.