JULY 2005 PBAC OUTCOMES – POSITIVE RECOMMENDATIONS

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ABACAVIR 600 mg – LAMIVUDINE 300 mg tablet, Kivexa® GlaxoSmithKline Australia Pty Ltd Major submission	Antiviral for HIV/AIDS	Section 100 (Highly Specialised Drug) Treatment in combination with other antiretroviral agents, of HIV infection in patients over 12 years of age, with: (a) CD4 cell counts of less than 500 per cubic millimetre; or (b) viral load of greater than 10,000 copies per mL.	Consistent with its policy on fixed dose combination products, the PBAC recommended listing on a cost-minimisation basis compared to the corresponding strengths of the individual components as the data from the two prospectively designed non-inferiority trials indicate once daily Kivexa as requested has similar safety and efficacy compared to concomitant abacavir 600 mg and lamivudine 300 mg daily.
ACICLOVIR, tablet, 200 mg, Aciclovir-BC®, Biochemie Australia; Acihexal®, Hexal Australia Pty Ltd; Acyclo-V 200®, Alphapharm Pty Ltd; Chem mart Aciclovir®, Chem mart Pty Limited; GenRx Aciclovir®, GenRx Pty Ltd; Lovir®, Douglas Pharmaceuticals Australia Ltd; Terry White Chemists Aciclovir®, Terry White Chemists; Zyclir 200®, Arrow Pharmaceuticals Limited; Zovirax 200 mg®, GlaxoSmithKline Australia Pty Ltd Minor submission	Anti-viral agent	Delete the sentence: “Pathology reports from accredited laboratories must be available for audit by the HIC” and the NOTE: “Patients who commenced on suppressive therapy prior to 1 May 2004, and who are continuing on suppressive therapy, are not required to have pathology reports of microbiological confirmation available for audit by the HIC.”	The PBAC agreed to the request from the HIC to delete the sentence and note from the listing for episodic or suppressive therapy for genital herpes following advice that any conditions in PBS restrictions which relate to events which occur after the prescription is written are of no practical effect.
AMINO ACID FORMULA with VITAMINS and MINERALS without	A food for inborn errors of metaobolism		The PBAC had no objection to the Secretariat decision to agree to the

PHENYLALANINE, liquid formula, 130 mL, PKU Express Liquid® Vitaflo Australia Pty Ltd Minor submission			sponsor's request to change the name of the product from PKU Express Active to PKU Express Liquid, or to the reduction in volume from 150 mL to 130 mL.
ANASTROZOLE 1 mg tablet, Arimidex® AstraZeneca Pty Ltd Major submission	Anti-cancer drug	Restricted Benefit for Treatment of hormone-dependent breast cancer in post-menopausal women	The PBAC recommended the listing for anastrozole be extended to include all post-menopausal women with hormone-dependent early breast cancer on the basis of acceptable cost-effectiveness compared with tamoxifen. While the ATAC trial showed no overall survival gain, the PBAC accepted that in the long-term, sufficiently large incremental survival benefits could be expected, in the most part due to the prevention of contralateral breast cancer, to justify the incremental costs.
BUPRENORPHINE 5 mg, 10 mg, and 20 mg transdermal patches, Norspan® Mundipharma Pty Ltd Major submission	Opioid analgesic	Restricted Benefit for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.	The PBAC recommended listing on a cost-minimisation basis, concluding the indirect comparisons involving immediate release oxycodone/paracetamol and placebo as the common references submitted indicated buprenorphine transdermal patches were similar to oxycodone hydrochloride controlled release tablets in terms of pain management. The equi-effective doses are transdermal buprenorphine 5 mg, 10 mg and 20 mg every seven days and oxycodone hydrochloride controlled release 10 mg, 20 mg and 30 mg twice daily, respectively.

CALCIUM FOLINATE, injection equivalent to 300 mg folinic acid in 30 mL, 4, Leucovorin® Mayne Pharma Pty Ltd Minor submission	Fluorouracil modulator	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list this strength of calcium folinate to accommodate protocols that use 200 mg/m^2.
CLOZAPINE tablets, 25 mg and 100 mg, Clozaril® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Atypical antipsychotic drug	Section 100 (Highly Specialised Drugs) listing for schizophrenia in patients who are: (a) non-responsive to other neuroleptic agents; or (b) intolerant of other neuroleptic agents.	The PBAC had no objection to the Secretariat decision to list an additional pack size of 28 tablets in a blister pack for use in dispensing from community pharmacies and for weekly dispensing to patients in their first 18 weeks of therapy under the usual Section 100 (Highly Specialised Drugs) arrangements.
COAL TAR topical emulsion, Exorex® EpiTan Limited Major submission	Psoriasis cream	Resubmission for unrestricted benefit listing for the treatment of psoriasis of skin and scalp	The PBAC recommended listing on the basis of acceptable cost-effectiveness compared with extemporaneous preparations containing coal tar.
DOXORUBICIN HYDROCHLORIDE, solution for IV injection or intravesical administration, 100 mg in 50 mL, 200 mg in 100 mL, Doxorubicin Ebewe® InterPharma Pty Ltd Minor submission	Anti-cancer agent	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list two new larger strengths of a currently PBS-listed item.
EPIRUBICIN HYDROCHLORIDE, solution for IV injection, 200 mg in	Anti-cancer agent	Unrestricted listing	The PBAC had no objection to the Secretariat decision to listing this new

100 mL, Epirubicin Ebewe® InterPharma Pty Ltd Minor submission			strength of epirubicin hydrochloride.
EPLERENONE, 25 mg and 50 mg tablets, Inspra® Pfizer Australia Limited Major submission	Heart disease drug	Authority Required listing to reduce the risk of cardiovascular death in combination with standard medical therapy in patients who have evidence of heart failure and left ventricular impairment within 3-14 days of an acute myocardial infarction.	The PBAC recommended listing as an authority required benefit for heart failure with a left ventricular ejection fraction of 40% or less occurring within 3-14 days following an acute myocardial infarction, on the basis of acceptable cost-effectiveness compared with placebo. The PBAC considered that it would be possible for PBS subsidy of eplerenone to commence after 14 days of the acute myocardial infarction (for example after discharge from hospital), so long as this is a continuation of eplerenone treatment which had commenced within the required timeframe specified in the restriction.
EZETIMIBE with SIMVASTATIN, tablets 10/40 mg and 10/80 mg, Vytorin® Merck, Sharp & Dohme Minor submission	Lipid lowering drug combination	Change restriction to remove requirement that patient must be stabilised on ezetimibe with 40 mg of a statin, before being transferred to combination product.	The PBAC recommended that the previously recommended restriction for ezetimibe with simvastatin be amended to allow for patients with coronary heart disease or diabetes mellitus who were inadequately controlled after three months treatment at a daily dose 40 mg or greater of any statin to commence treatment on Vytorin® (ezetimibe with simvastatin).
FAMCICLOVIR, tablets, 125 mg (40 tablets) and 250 mg (56 tablets), Famvir®	Anti-viral agent	Delete the sentence: “Pathology reports from accredited laboratories must be available for audit by the	The PBAC agreed to the request from the HIC to delete the sentence and note from the listing for episodic or suppressive

Novartis Pharmaceuticals Australia Pty Ltd Minor submission		HIC" and the NOTE: "Patients who commenced on suppressive therapy prior to 1 May 2004, and who are continuing on suppressive therapy, are not required to have pathology reports of microbiological confirmation available for audit by the HIC."	therapy for genital herpes following advice that any conditions in PBS restrictions which relate to events which occur after the prescription is written are of no practical effect.
FLUTICASONE PROPIONATE, oral pressurised inhalation, 250 mcg per dose, 120 doses; powder for oral inhalation in breath actuated device, 500 mcg per dose, 60 doses, Flixotide® GlaxoSmithKline Australia Pty Ltd Minor submission	Corticosteroid used as a preventative treatment in asthma	Sponsor requested retention of this item on the PBS following request at previous PBAC meeting to delete.	The PBAC agreed to the sponsor's request to retain these items on the PBS, but with the number of repeats reduced from 5 to 1.
FOLLITROPIN BETA, solution for injection, 200 i.u. in 0.5 mL, single use vial, Puregon® Organon (Australia) Pty Limited Minor submission	Infertility treatment	Restricted benefit listing for the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.	The PBAC had no objection to the Secretariat decision to list the 200 i.u. strength vial temporarily as a Section 85 item as the company is unable to fulfil orders for the 100 and 150 i.u. vial strengths, and expects to eventually seek PBS listing for new cartridge presentations of follitropin beta for the male indication.
GLUCOSE INDICATOR – BLOOD ELECTRODE STRIPS 50, glucose measuring strips, True Track® DiaCare International Pty Ltd	Testing strips for use by diabetics	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list this product as an unrestricted benefit with a maximum quantity of 2 packs and 5 repeats.

Minor submission			
HYDROMORPHONE capsules (controlled release), 12 mg, 16 mg, 24 mg and 32 mg, Palladone® XL Mundipharma Pty Ltd (Australia) Major submission	Opioid analgesic	Restricted Benefit listing for Chronic severe disabling pain not responding to non-narcotic analgesics.	The PBAC recommended listing on a cost-minimisation basis, concluding the indirect comparison involving immediate release hydromorphone as the common reference submitted indicated hydromorphone hydrochloride controlled release capsules were no worse than oxycodone hydrochloride controlled release tablets in pain management. The equi-effective doses are hydromorphone hydrochloride controlled release 1 mg and oxycodone hydrochloride controlled release 4 mg.
IMATINIB MESYLATE, tablet, 100 mg and 400 mg (base), Glivec® Novartis Pharmaceuticals Australia Pty Ltd Minor submission .	Treatment for chronic myeloid leukaemia (CML) and gastrointestinal stromal tumours.	Requests from the Haemotology Society of Australia and New Zealand (HSANZ) to review some of the PBS regulations governing the use of imatinib in CML.	The PBAC accepted the HSANZ's request for a change to the method of diagnosis in the initiation criteria to allow the provision of quantitative PCR analysis of peripheral blood instead of a cytogenetic study of bone marrow. The PBAC also recommended that patients, in whom it has not been possible to obtain a bone marrow sample for testing (dry tap) on two occasions, could have Q-PCR of a blood sample to measure the level of bcr-abl. The PBAC agreed that the restriction should also include a reference to the level of bcr-abl that corresponds to a major cytogenetic response. Restriction yet to be finalised. A weblink will be provided on finalisation.

LANREOTIDE, 60 mg, 90 mg and 120 mg sc injection, Somatuline Autogel® Ipsen Pty Ltd Major submission	Peptide analogue use in the treatment of acromegaly and carcinoid syndrome	Section 100 Highly Specialised Drug for the treatment of symptoms of carcinoid syndrome associated with carcinoid tumours.	The PBAC recommended listing for the treatment of carcinoid tumour on a cost-minimisation basis compared with octreotide acetate modified release injection (Sandostatin LAR®). A dose relativity of 4.67:1 for lanreotide autogel versus octreotide LAR was considered appropriate and is consistent with the ratio between these products established for the acromegaly restriction.
LIGNOCAINE HYDROCHLORIDE, injection, 100 mg in 5 mL, Pfizer Pty Ltd Minor submission	Local anaesthetic	Unrestricted (General and Dental List) Emergency Drug (Doctor's Bag) Supplies	The PBAC had no objection to the Secretariat decision to list maximum quantities of 5 ampoules for general and dental listings and for Emergency (doctor's bag) supply as Pfizer can only supply it in packs of five ampoules.
METFORMIN HYDROCHLORIDE with GLIBENCLAMIDE, tablet, 250 mg-1.25 mg Glucovance® Alphapharm Pty Ltd Minor submission	Oral hypoglycaemic	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list this new lower strength of the currently PBS-listed product which will reduce the requirement for breaking tablets of the higher strength.
METHOTREXATE, solution for IV injection, 500 mg in 5 mL, 1 g in 10 mL, 5 g in 50 mL, Methotrexate Ebewe® InterPharma Pty Ltd Minor submission	Anti-cancer agent	Unrestricted listing	The PBAC had no objection to the Secretariat decision to list three new higher strengths of a currently listed PBS item.

MIRTAZAPINE, tablets (orally disintegrating), 15 mg, 30 mg, 45 mg, Avanza SolTab® British Pharmaceuticals Pty Ltd Minor submission	Anti-depressant	Restricted benefit for depressive disorders.	The PBAC had no objection to the Secretariat decision to list a new soluble tablet formulation and for lower and higher strengths of the currently listed PBS item, which provides an alternative dosage form for patients unable to swallow conventional tablets or capsules. The PBAC had no objection to the application of separate PBS item codes for this formulation.

NARCOTIC ANALGESICS HYDROMORPHONE HYDROCHLORIDE, tablet, 2 mg, 4 mg, 8 mg, oral liquid 1 mg per mL, Dilaudid®, Abbott Australasia Pty Ltd; METHADONE HYDROCHLORIDE, tablet, 10 mg, injection 10 mg in 1 mL, GlaxoSmithKline Australia Pty Ltd; MORPHINE HYDROCHLORIDE, oral solution, 2 mg per mL, 5 mg per mL, 10 mg per mL, Ordine®, Mundipharma Pty Ltd; MORPHINE SULFATE, controlled release tablets (all strengths except the 200 mg strength), sachets containing controlled release granules for oral suspension (all strengths except the 200 mg strength), and controlled release capsules (all strengths); capsules containing sustained release pellets (all strengths), MS Contin®, Mundipharma Pty Ltd; Kapanol®, GlaxoSmith Kline Australia Pty Ltd; MORPHINE SULFATE, tablet, 30 mg, Anamorph®, Fawns & McAllan Pty Ltd; OXYCODONE, suppository, 30 mg, Proladone®, Pharmalab; OXYCODONE HYDROCHLORIDE, tablet, 5 mg; capsule, 5 mg, 10 mg, 20 mg, oral solution, 5 mg per 5 mL, Endone®, Sigma Pharmaceuticals Pty Ltd; OxyNorm®, Mundipharma Pty Ltd; OXYCODONE HYDROCHLORIDE, controlled release tablet, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, OxyContin®,	Opioid analgesics	Amend NOTE (iv) by inclusion of the phrase 'by the patient', to read: (iv) First application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation **by the patient** with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than three months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation is to be provided at the time of application; or	The PBAC recommended the above amendment to clarify the agreed intent that the consultation be between the patient and another medical practitioner. The PBAC recalled that, in early April 2005, the medical practitioner groups had advised there were medico-legal issues associated with prescribing narcotic analgesics following consultation between two medical practitioners with respect to a patient not known to one party.

Mundipharma Pty Ltd Minor submission			
OXALIPLATIN, solution for IV infusion, 50 mg in 10 mL, 100 mg in 20 mL, Eloxatin® Sanofi-Aventis Australia Group Minor submission	Anti-cancer agent	Authority required listing for metastatic colorectal cancer in patients with WHO performance status of 2 or less, to be used in combination with 5-fluorouracil and folinic acid; and as adjuvant treatment, in combination with 5-fluorouracil and folinic acid, of Stage III (Duke's C) colon cancer after complete resection of the primary tumour.	The PBAC had no objection to the Secretariat decision to list a new solution formulation of a currently listed PBS item, which will reduce the number of preparation steps required.
<u>PALLIATIVE CARE LISTINGS</u> DIAZEPAM, tablets, 2 mg and 5 mg, Antenax®, Alphapharm Pty Ltd; Diazepam-DP®, Douglas Pharmaceuticals Australia Ltd; Ducene®, Sauter Laboratories (Australia) Pty Ltd; Valium®, Roche Products Pty Ltd; Valpam®, Arrow Pharmaceuticals Ltd; OXAZEPAM, tablets, 15 mg and 30 mg, Alepam®, Alphapharm Pty Ltd; Murelax®, Fawns and McAllan Pty Ltd; Serepax®, Sigma Pharmaceuticals Pty Limited; Minor submission	Anxiolytic agents	Authority required listing for initial supply (for up to 4 months) for palliative care patients where anxiety is a problem; and for continuing supply for palliative care patients where anxiety is a problem, and where consultation with a palliative care specialist or service has occurred.	The PBAC agreed to a request from the Palliative Care Medications Working Group that these agents be included in the Palliative Care Schedule to allow access for palliative care patients who were unable to access increased quantities of the medication via the criteria for granting authorities for increased maximum quantities and/or repeats associated with the current PBS listing.
<u>PALLIATIVE CARE LISTINGS</u>	Hypnotic agents	Authority required listing for initial	The PBAC agreed to a request from the

NITRAZEPAM, tablet, 5 mg, Alodorm®, Alphapharm Pty Ltd; Mogadon®, ICN Pharmaceuticals Australasia Pty Ltd; TEMAZEPAM, tablet, 10 mg, Temaze®, Alphapharm Pty Ltd, Temtabs®, Fawns and McAllan Pty Ltd; Normison®, Sigma Pharmaceuticals Pty Ltd Minor submission		supply (for up to 4 months) for palliative care patients where insomnia is a problem; and for continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred.	Palliative Care Medications Working Group that these agents be included in the Palliative Care Schedule to allow access for palliative care patients who were unable to access increased quantities of the medication via the criteria for granting authorities for increased maximum quantities and/or repeats associated with the current PBS listing.
<u>PALLIATIVE CARE LISTINGS</u> DICLOFENAC SODIUM, tablets (enteric coated), 25 mg and 50 mg, Chem mart Diclofenac, Chem mart Pty Ltd; Clonac® 25 and Clonac 50, Arrow Pharmaceuticals Pty Ltd ; Diclofenac-BC®, Biochemie Australia; Diclohexal®, Hexal Australia Pty Ltd; Dinac®, Douglas Pharmaceuticals Australia Ltd; Fenac®, Alphapharm Pty Ltd; GenRx Diclofenac®, GenRx Pty Ltd; Terry White Chemists Diclofenac®, Terry White Chemists; Voltaren® 25 and Voltaren 50, Novartis Pharmaceuticals Australia Pty Ltd; and suppository 100 mg, Voltaren® 100, Novartis Pharmaceuticals Australia Pty Ltd; DIFLUNISAL, tablets, 250 mg and 500 mg, Dolobid®, Merck Sharp & Dohme (Australia) Pty Ltd; IBUPROFEN, tablets, 200 mg and 400 mg, Rafen® 200, Alphapharm Pty Ltd; Brufen®, Abbott Australasia Pty Ltd;	Non-steroidal anti-inflammatory drugs	Authority required listing for initial supply (for up to 4 months) for palliative care patients where severe pain is a problem; and for continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.	The PBAC agreed to a request from the Palliative Care Medications Working Group that these agents 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.

INDOMETHACIN, capsule, 25 mg, Arthrexin®, Alphapharm Pty Ltd; Indocid®, Merck Sharp & Dohme (Australia) Pty Ltd and suppository 100 mg, Indocid®, Merck Sharp & Dohme (Australia) Pty Ltd; NAPROXEN, tablets, 250 mg, 500 mg, 750 mg (sustained release) and 1 g (sustained release), Inza® 250 and Inza 500, Alphapharm Pty Ltd; Naprosyn®, Naprosyn SR750 and NaprosynSR1000, Roche Products Pty Ltd; Proxen® 750, Proxen SR 1000, Macarthur Research; NAPROXEN SODIUM, tablet, 550 mg, Crysanal®, Macarthur Research; Anaprox 550®, Roche Products Pty Ltd; SULINDAC, tablets, 100 mg and 200 mg, Aclin® and Aclin 200, Alphapharm Pty Ltd Minor submission			
PIOGLITAZONE HYDROCHLORIDE, tablet, 15 mg, 30 mg and 45 mg, Actos® Eli Lilly Australia Pty Ltd Minor submission	Oral hypoglycaemic agent	Delete the sentence: “Pathology reports from accredited laboratories must be available for audit by the HIC”.	The PBAC agreed to the request from the HIC to delete this sentence from the listings for pioglitazone hydrochloride following advice that any conditions in PBS restrictions which relate to events which occur after the prescription is written are of no practical effect.
POLYVINYL ALCOHOL, eye drops (contains sodium chloride and hydrogen peroxide as preservative),	Lubricant eye drop	Restricted benefit listing for severe dry eye syndrome, including Sjogren’s syndrome.	The PBAC had no objection to the Secretariat decision to list a new formulation of a non-prescription ocular

14 mg per mL (1.4%), 15 mL, Vistil®, 30 mg per mL (3.0%) 15 mL, Vistil Forte® AFT Pharmaceuticals Pty Ltd Minor submisson			lubricant, containing OXYD (sodium chloride 0.005% and hydrogen peroxide 0.001%) as preservative.
PETHIDINE HYDROCHLORIDE, injection, 100 mg in 2 mL, Mayne Pharma Pty Ltd Minor submission	Opioid analgesic	Deletion from Dr's bag list	The PBAC agreed that implementation of the deletion of this item from the Emergency Drug (Doctor's Bag) Supplies, recommended at the March 2005 meeting, be deferred until 1 April 2006, to allow sufficient time for prescribers to be advised and educated in managing the non-availability of the injection for emergencies. The NPS was requested to assist in advising practitioners of appropriate alternatives in emergency pain management.
PREGABALIN, 75 mg, 150 mg and 300 mg capsules, Lyrica® Pfizer Australia Pty Ltd Major submission	An anti-epileptic drug, also used for treatment of neuropathic pain	Authority Required listing for the treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.	The PBAC recommended listing on a cost-minimisation basis compared with gabapentin, with the equi-effective doses being pregabalin 349 mg daily and gabapentin 1188 mg daily.
ROSIGLITAZONE MALEATE tablet, 4 mg and 8 mg, Avandia® GlaxoSmithKline Australia Pty Ltd Minor submission	Oral hypoglycaemic agent	Delete the sentence: "Pathology reports from accredited laboratories must be available for audit by the HIC".	The PBAC agreed to the request from the HIC to delete this sentence from the listings for rosiglitazone maleate following advice that any conditions in PBS restrictions which relate to events which occur after the prescription is written are of no practical effect.

SIROLIMUS, tablets, 1mg and 2 mg, and oral solution 1 mg per mL, 60 mL, Rapamune® Wyeth Australia Pty Ltd Minor submission	Immunosuppressive agent		The PBAC had no objection to the Secretariat decision to change the sirolimus listing to make it consistent with the TGA-approved indications, as recommended by PBAC at its March 2005 meeting, by deletion of the words 'and treatment of' from the Section 100 listing.
STRONTIUM RANELATE, 2 gram, sachets, Protos® Servier Laboratories (Australia) Pty Ltd Major submission	Treatment for osteoporosis	Authority Required listing for the treatment of established postmenopausal osteoporosis ie prevalent fracture.	The PBAC recommended listing on a cost-minimisation basis compared to alendronate for the outcome of morphometric vertebral fracture. The equi-effective doses are strontium 2 g daily and alendronate 70 mg weekly. The PBAC recognised that, given the different mechanism of action of other listed antiresorptive drugs, there was a potential for strontium to be added to, as well as substitute for current therapy with bisphosphonates or selective oestrogen receptor modulators. Thus, the PBAC recommended that the restriction preclude PBS subsidisation of concomitant therapy with listed PBS antiresorptives.
TERBINAFINE HYDROCHLORIDE, tablet, 250 mg (base), Lamisil®, Novartis Pharmaceuticals Australia Pty Ltd; Zabel® Alphapharm Pty Ltd Minor submission	Anti-fungal agent	Delete the sentence: "Pathology reports from accredited laboratories must be available for audit by the HIC".	The PBAC agreed to the request from the HIC to delete this sentence following advice that any conditions in PBS restrictions which relate to events which occur after the prescription is written are of no practical effect.

VALACICLOVIR HYDROCHLORIDE, tablet, 500 mg (base), Valtrex®, GlaxoSmithKline Australia Pty Ltd Minor submission	Anti-viral agent	Delete the sentence: “Pathology reports from accredited laboratories must be available for audit by the HIC” and the NOTE: “Patients who commenced on suppressive therapy prior to 1 May 2004, and who are continuing on suppressive therapy, are not required to have pathology reports of microbiological confirmation available for audit by the HIC.”	The PBAC agreed to the request from the HIC to delete the sentence and note from the listing for episodic or suppressive therapy for genital herpes following advice that any conditions in PBS restrictions which relate to events which occur after the prescription is written are of no practical effect.