

**JULY 2008 PBAC OUTCOMES - "1<sup>st</sup> time" Decisions not to Recommend**

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>Adalimumab, injection 40 mg in 0.8 mL, pre-filled syringe &amp; pre-filled pen, (Humira<sup>®</sup>)</p> <p>Abbott Australasia Pty Ltd</p> <p>Major submission</p>	<p>Chronic plaque psoriasis</p>	<p>To extend the current Authority Required listing to include the treatment of patients with severe chronic plaque psoriasis.</p>	<p>The PBAC rejected the submission because of insufficient evidence of non-inferiority against appropriate comparator, efalizumab.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor looks forward to working with the PBAC to ensure a successful listing for chronic plaque psoriasis.</p>
<p>Alglucosidase alfa-rch, powder for IV infusion, 50 mg, (Myozyme<sup>®</sup>)</p> <p>Genzyme Australasia Pty Ltd</p> <p>Major submission</p>	<p>Pompe disease</p>	<p>Section 100 - Highly Specialised Drug or to be considered for Life Saving Drug Program <i>for the treatment of a patient with Pompe disease, who meets certain criteria.</i></p>	<p>The PBAC rejected the application for PBS listing but recommended Government consider including alglucosidase on the Life Saving Drugs Program for use in infantile onset Pompe disease. The application for listing on the Life Saving Drugs Program for use in adult onset Pompe disease was rejected because the Committee was unable to form a view on the clinical efficacy as there was insufficient data present at the time of the submission.</p>
		<p>Sponsor's comments:</p>	<p>Genzyme will support the application for the listing of Myozyme in adult onset patients with new data recently made available.</p>

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<p>Atomoxetine hydrochloride, capsules, all strengths, (Strattera<sup>®</sup>)</p> <p>Eli Lilly Australia Pty Ltd</p> <p>Minor submission</p>	<p>Attention Deficit Hyperactivity Disorder</p>	<p>Initial treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed by a paediatrician or psychiatrist according to the DSM-IV criteria in children 6 years of age and older, adolescents and adults, where:</p> <p>(a) treatment with dexamphetamine sulfate or methylphenidate hydrochloride poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information:</p> <p>(1) The patient has a history of substance abuse or misuse (other than alcohol); and/or</p> <p>(2) The patient has comorbid motor tics or Tourette's Syndrome; and/or</p> <p>(3) The patient has comorbid severe anxiety diagnosed according to the DSM-IV; or</p> <p>(b) treatment with dexamphetamine sulfate or methylphenidate hydrochloride has resulted in the development or worsening of a comorbid mood disorder (diagnosed according to the DSM-IV criteria i.e. anxiety disorder, obsessive compulsive disorder, depressive disorder) of a severity necessitating permanent stimulant treatment withdrawal; or where the combination of stimulant treatment with another agent would pose an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal; or</p> <p>(c) treatment with dexamphetamine sulfate AND methylphenidate hydrochloride has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:</p> <p>(1) Adverse effects on growth and weight; and/or</p> <p>(2) Adverse effects on sleep including insomnia; and/or</p> <p>(3) Adverse effects on appetite including anorexia.</p>	<p>The PBAC rejected the submission because of insufficient evidence of clinical and cost-effectiveness in patients diagnosed as an adult</p>
		<p>Sponsor's comments:</p>	<p>Nil</p>

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<p>Doxorubicin hydrochloride, pegylated liposomal, suspension for I.V. infusion 20 mg in 10 mL, suspension for I.V. infusion 50 mg in 25 mL, (Caelyx<sup>®</sup>)</p> <p>Schering-Plough Pty Ltd</p> <p>Major submission</p>	<p>Multiple myeloma</p>	<p>To extend the current Authority Required listing to include the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.</p>	<p>The PBAC rejected the submission because of uncertain clinical benefit and a high and uncertain cost-effectiveness ratio.</p>
<p>Eculizumab, solution for I.V infusion, 300 mg in 30 mL, (Soliris<sup>®</sup>)</p> <p>Alexion Pharmaceuticals</p> <p>Major submission</p>	<p>Paroxysmal nocturnal haemoglobinuria</p>	<p>Section 100 or to be considered for Life Saving Drug Program for the treatment of patients with paroxysmal nocturnal haemoglobinuria to reduce haemolysis.</p>	<p>The PBAC rejected the submission for inclusion on the PBS because of unacceptably high and highly uncertain cost-effectiveness. The PBAC also rejected the application for inclusion in the Life Saving Drugs Program because it does not meet several of the criteria for that program.</p>
<p>Etanercept, injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL, injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL, injections 50 mg in 1 mL single use pre-filled syringes, 4, (Enbrel<sup>®</sup>)</p> <p>Wyeth Australia Pty Ltd</p>	<p>Psoriasis</p>	<p>1. To request a change to the initial criteria for psoriasis allowing patients with a PASI of 50 at week 12, a further 12 weeks treatment and those achieving a PASI of 75 after the end of this 12-week period to qualify for continuing treatment.</p> <p>2. To request a change to the continuing criteria for etanercept for psoriasis to allow patients achieving a PASI of 75 at week 12 to receive continuous therapy or intermittent therapy.</p>	<p>The PBAC rejected the submission on the basis of uncertainty in the clinical data and economic model, resulting in a high and uncertain cost-effectiveness ratio.</p>
<p>Sponsor's comments:</p>	<p>The sponsor intends to clarify the decision with the PBAC and will be considering its position regarding any future course of action.</p>	<p>Sponsor's comments:</p>	<p>The sponsor disagrees with the PBAC's current position. The sponsor is committed to working with the PBAC to address any areas of their uncertainty which require clarification.</p>

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Major submission		Sponsor's comments:	The sponsor needs to clarify the decision with the PBAC and refers you to its own website at <a href="http://www.wyeth.com.au/go/top-navigation/media-room">http://www.wyeth.com.au/go/top-navigation/media-room</a> for further comment.
Imiquimod, cream, 50 mg per g (5%), 250 mg single use sachets, 12, (Aldara <sup>®</sup> )  iNova Pharmaceuticals (Australia) Pty Ltd  Major submission	Skin cancer	To extend the current Authority Required listing to include the treatment of solar keratosis (SK) on the face or scalp in a patient with normal immune function who has multiple clinically evident SK lesions and requires topical drug treatment as field therapy.	The PBAC rejected the submission because of uncertain evidence of effectiveness and safety over the alternative therapy, 5-fluorouracil gel, and the resulting uncertain cost-effectiveness.
		Sponsor's comments:	Nil
Infliximab, powder for IV infusion, 100 mg, (Remicade <sup>®</sup> )  Schering-Plough Pty Ltd  Major submission	Rheumatoid arthritis	To allow dose escalation to 5 mg/kg in rheumatoid arthritis patients who have failed to respond to an initial dose of 3 mg/kg, and in patients who have responded to treatment at a dose of 3 mg/kg but subsequently experience a disease flare.	The PBAC rejected the application on the basis of uncertain clinical effectiveness and consequently uncertainty in establishing cost-minimisation against existing therapies.
		Sponsor's comments:	Nil
Letrozole, tablet, 2.5 mg, (Femara <sup>®</sup> )  Novartis Pharmaceuticals Australia Pty Ltd  Minor submission	Breast cancer	To request removal of the requirement in the letrozole restriction to commence therapy within 6 months of ceasing tamoxifen in post menopausal women with early breast cancer.	The PBAC rejected the submission because of uncertain clinical benefit and potential for harm in patients who are started on letrozole after finishing tamoxifen several years previously and are not currently receiving any treatment.
		Sponsor's comments:	Nil

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<p>Pramipexole hydrochloride, tablet, 0.125 mcg, 0.250 mcg, 1 mg, (Sifrol<sup>®</sup>)</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Major submission</p>	<p>Parkinson's disease</p>	<p>To extend the current Restricted benefit listing to include the treatment of Parkinson's disease, as monotherapy.</p>	<p>The PBAC rejected the request to extend the PBS-subsidy of pramipexole to include early Parkinson disease because of insufficient evidence to substantiate the claim that pramipexole is non-inferior to cabergoline or levodopa-carbidopa.</p>
		<p>Sponsor's comments:</p>	<p>Boehringer Ingelheim intends to clarify the decision with the PBAC and will be considering its position regarding any future re-submission.</p>
<p>Rituximab, solution for I.V 500 mg in 50 mL, (Mabthera<sup>®</sup>)</p> <p>Roche Products Pty Ltd</p> <p>Minor submission</p>	<p>Rheumatoid arthritis</p>	<p>To request changes to the restrictions for all bDMARDs for rheumatoid arthritis to include Disease Activity Score 28 Joint Count (DAS28) of less than 3.2 or an improvement over baseline DAS 28 of greater than 1.2 in the definition of response as an alternative definition of response.</p>	<p>The PBAC rejected the submission because the cost-effectiveness of rituximab has been assessed on the basis of a response criteria built around an ACR50, and the cost-effectiveness of a treatment restriction based upon these alternative criteria is unknown.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor will be considering its position regarding any future course of action.</p>
<p>Temsirolimus, set containing 1 vial of powder for I.V infusion 25 mg and 1 vial of diluent, (Torisel<sup>®</sup>)</p> <p>Wyeth Australia Pty Ltd</p> <p>Major submission</p>	<p>Kidney cancer</p>	<p>Section 100 – Public and Private Hospital Authority Required for the treatment of advanced renal cell carcinoma with a poor prognosis, who meet certain criteria.</p>	<p>The PBAC rejected the application on the basis of an unacceptably high and uncertain incremental cost-effectiveness ratio.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor will continue to work with the PBAC to achieve a successful listing.</p>