

JULY 2004 PBAC OUTCOMES - "1st time" Decision not to Recommend

DRUG AND FORM	DRUG USE ANDTYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
<p>ALEFACEPT IM injection, 15 mg, IV injection 7.5 mg, Amevive® Biogen Idec Australia Pty Ltd</p>	<p>Used for the treatment of chronic plaque psoriasis</p>	<p>Authority required listing for the treatment by a dermatologist of adults 18 years and over who have been diagnosed with severe chronic plaque psoriasis who meet certain criteria.</p>	<p>The PBAC rejected the application because of unfavourable and uncertain cost-effectiveness.</p>
		<p><i>Sponsor's comments</i></p>	<p>The sponsor intends to clarify the issue with the PBAC and then consider its course of action.</p>
<p>AMINO ACID FORMULA without PHENYLALANINE powder 400g. Nutricia Australia Pty Ltd</p>	<p>A food for inborn errors of metabolism</p>	<p>Restricted benefit listing for phenylketonuria.</p>	<p>The application was rejected because of uncertain clinical benefit.</p>
		<p><i>Sponsor's comments</i></p>	<p>The sponsor will be considering its position regarding any future course of action.</p>

<p>EPOPROSTENOL vials 0.5 mg, 1.5 mg with 2 vials 50 mL diluent with filter, Flolan®</p> <p>GlaxoSmithKline Australia Pty Ltd</p>	<p>A form of prostacyclin or prostaglandin PGI₂ used for the treatment of primary pulmonary hypertension.</p>	<p>Section 100 (Highly Specialised Drug) public and private hospital authority required listing for Initiation therapy for patients with primary pulmonary hypertension who meet certain criteria and who have failed to respond to treatment with bosentan or;</p> <p>where bosentan is contraindicated or has been ceased due to intolerable adverse events or;</p> <p>who have established severe right heart failure</p> <p>Continuation therapy for patients with primary pulmonary hypertension who meet certain criteria.</p>	<p>The PBAC rejected the application because of unacceptable cost-effectiveness.</p>
		<p><i>Sponsor's comments</i></p>	<p>The sponsor needs to clarify the decision with the PBAC. Please refer to the GlaxoSmithKline website for further information:</p> <p>www.gsk.com.au</p>
<p>PAROXETINE HYDROCHLORIDE, controlled release tablets, 12.5 mg (base), 25 mg (base), Aropax CR®, Paroxat CR®,</p> <p>GlaxoSmithKline Australia Pty Ltd</p>	<p>A selective serotonin reuptake inhibitor</p>	<p>Restricted benefit listing <i>for major depressive disorders and panic disorder</i></p>	<p>The PBAC rejected the application because of the potential to cause confusion over the different indications which would be PBS-subsidised for the two types of paroxetine formulations.</p>
		<p><i>Sponsor's comments</i></p>	<p>The sponsor disagrees with the decision and needs to clarify the decision with the PBAC.</p>