

July 2005 PBAC OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENT
<p>DOCETAXEL 20 mg and 80 mg Injection, Taxotere®</p> <p>Sanofi Aventis Group</p> <p>Major submission</p>	<p>Anti-cancer drug used for the treatment of breast cancer, ovarian cancer, prostate cancer and lung cancer.</p>	<p>Authority Required listing <i>for the adjuvant treatment of operable node-positive breast cancer in combination with and anthracycline (eg doxorubicin hydrochloride) and cyclophosphamide.</i></p>	<p>The PBAC deferred the submission to seek clarification about certain aspects of uncertainty with the economic model.</p>
		<p>Sponsor's comments</p>	<p>The sponsor will be responding to the PBAC's request.</p>
<p>INSULIN DETEMIR 100 IU per mL, Levemir®</p> <p>Novo Nordisk Pharmaceuticals Pty Ltd</p> <p>Major submission</p>	<p>Long acting insulin used to treat diabetes.</p>	<p>Authority Required listing for the treatment of diabetes mellitus where used as basal insulin in combination with meal-related short-or rapid-acting insulin.</p>	<p>The PBAC deferred the application and resolved to ask the sponsor how it wishes to proceed in the absence of the sponsor's precondition for listing, namely a recommendation to list insulin glargine.</p>
		<p>Sponsor's comments</p>	<p>The sponsor is considering its position regarding any future course of action.</p>
<p>LATANOPROST and TIMOLOL, 50 mcg/mL/5 mg/mL, eye drops, Xalacom®</p> <p>Pfizer Australia Pty Ltd</p>	<p>Anti glaucoma drug.</p>	<p>Restricted Benefit listing for the reduction of elevated intraocular pressure in patients with open-angle glaucoma and ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins or</p>	<p>The PBAC deferred a decision on the listing to request that the sponsor provide a meta-analysis of two trials to include the results of a trial that became available at the time of the July PBAC meeting.</p>

Major submission		other intraocular pressure lowering medication.	
		Sponsor's comments	The sponsor will provide the requested information.