

March 2009 PBAC OUTCOMES – “1st time” decisions not to recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>AMINO ACIDS - SYNTHETIC, FORMULA Compound powder 400 g, EleCare[®] Vanilla</p> <p>Abbott Australasia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>To request Elecare[®] Vanilla be listed as an individual item in addition to the currently listed product, Elecare.</p>	<p>The PBAC rejected the request that Elecare Vanilla have a separate entry in the Schedule of Pharmaceutical Benefits on the basis there were minimal differences in the nutritional composition of Elecare and Elecare Vanilla.</p>
		<p>Sponsor's comments</p>	<p>The sponsor has no comment.</p>
<p>CLINDAMYCIN PHOSPHATE with BENZOYL PEROXIDE, gel, 10 mg (base) - 50 mg per gm (1% – 5%), 25 g, Duac[®] Once Daily Gel</p> <p>Stiefel Laboratories Pty Ltd</p> <p>Major submission</p>	<p>Acne treatment</p>	<p>Restricted benefit listing for the treatment of moderate acne vulgaris <i>with a minimum of 20 inflammatory lesions in patients with an inadequate response to at least two other topical therapies.</i></p>	<p>The PBAC rejected the application on the basis of uncertain cost effectiveness and uncertainty with its clinical place.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>
<p>DOCETAXEL, injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL and injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single use vial solvent 6 mL, Taxotere[®]</p>	<p>Anti-cancer drug</p>	<p>The removal of the NOTE restricting treatment to 10 cycles from the Authority required listing for treatment of metastatic carcinoma of the prostate.</p>	<p>The PBAC rejected the removal of the NOTE from the current listing for docetaxel for prostate cancer on the basis that no evidence was provided concerning the cost-effectiveness of treatment with docetaxel beyond 10 cycles.</p>

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<p>Sanofi-Aventis Australia Pty Ltd</p> <p>Minor submission</p>		<p>Sponsor's comments:</p>	<p>Sanofi-aventis disagrees with the decision and will work with the PBAC to ensure that the NOTE be removed, in order to allow those patients who are responding to treatment to continue to derive the ongoing benefits associated with docetaxel beyond the current 10 cycle restriction.</p>
<p>EZETIMIBE with SIMVASTATIN, tablet, 10 mg - 20 mg, Vytorin[®]</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Lipid lowering drug</p>	<p>Authority required (STREAMLINED) listing to include treatment in conjunction with dietary therapy and exercise in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) at a daily dose of 20 mg or greater and who meet the criteria of the General Statement for Lipid-Lowering Drugs Prescribed as Pharmaceutical Benefits.</p>	<p>The PBAC rejected the application on the basis of a lack of clinical need, given the availability of statins to provide a similar health benefit, that in terms of a cost-effectiveness evaluation the listing would provide currently available benefits at a higher cost, and the listing would place an additional significant financial burden on the PBS.</p>
<p>LEUPRORELIN ACETATE, suspension for subcutaneous injection (modified release), 7.5 mg injection set, 22.5 mg injection set, 30 mg injection set, 45 mg injection set, Eligard[®] 1 month, Eligard[®] 3 month, Eligard[®] 4 month, Eligard[®] 6 month</p> <p>Hospira Pty Ltd</p> <p>Minor submission</p>	<p>Anti-cancer drug</p>	<p>Restriction change from Authority Required to Authority Required (STREAMLINED).</p>	<p>The PBAC rejected the submission to change the current authority required listing of leuprorelin to a Streamlined authority listing as the submission had not presented any evidence to support the change to the listing.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>

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<p>METHYLNALTREXONE BROMIDE, vial, 12 mg in 0.6 mL (base), Relistor[®]</p> <p>Wyeth Australia Pty Ltd</p> <p>Major submission</p>	<p>Laxative agent</p>	<p>Authority required listing in the Palliative Care Section for initial and continuing treatment of opioid-induced constipation in patients who have failed to respond to or are unable to tolerate laxative therapies.</p>	<p>The PBAC rejected the application on the basis of high and uncertain cost-effectiveness.</p>
		<p>Sponsor's comments</p>	<p>Wyeth looks forwards to working with the PBAC to ensure a successful listing for the benefit of palliative care patients.</p>
<p>QUETIAPINE FUMARATE, tablet, 25 mg, 100 mg, 200 mg, 300 mg (base), Seroquel[®]</p> <p>AstraZeneca Pty Ltd</p> <p>Major submission</p>	<p>Bipolar disorder</p>	<p>To extend the current Authority required (Streamlined) listing for immediate release quetiapine to include treatment of a patient with depressive episodes associated with bipolar disorder.</p>	<p>The PBAC rejected listing on the basis the main comparator was inappropriate.</p>
		<p>Sponsor's comments:</p>	<p>The Sponsor understands the PBAC's position. There is a clinical need for quetiapine in this population and the Sponsor is committed to work with the PBAC to reach a satisfactory outcome.</p>
<p>VARENICLINE, tablet, 0.5 mg (titration pack), 1 mg (as tartrate), Champix[®]</p> <p>Pfizer Australia</p> <p>Minor submission</p>	<p>Smoking cessation agent</p>	<p>To amend the current Authority required listing by the addition of a note stating that a registration number for any support and counselling program is not required; and an additional criterion that a patient should have an appointment for a follow-up consultation.</p>	<p>The PBAC considered the addition of a NOTE to advise prescribers that patients do not require a registration number for any of the support and counselling programs prior to commencing varenicline to be unnecessary.</p> <p>With respect to inclusion of a requirement that the writing of a prescription for initial supply be restricted to those patients who had made a follow-up appointment, the PBAC considered such addition to be unnecessarily prescriptive on a matter that was essentially a part of the clinical responsibility of the prescriber.</p>

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