

NOVEMBER 2009 PBAC MEETING OUTCOMES – 1st time decisions not to recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>Aprepitant, pack containing 1 capsule 125 mg and 2 capsules 80 mg, Emend[®]</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Anti-nauseant</p>	<p>Extend the current Authority Required listing to include chemotherapy induced nausea and vomiting (CINV) associated with moderately emetogenic chemotherapy, which includes agents such as oxaliplatin, carboplatin and ifosfamide.</p>	<p>The PBAC rejected the submission on the basis of a high and uncertain cost-effectiveness ratio in the patient population requested.</p>
		<p>Sponsor's comments:</p>	<p>The Sponsor has no comment.</p>
<p>Botulinum toxin type A purified neurotoxin complex, lyophilised powder for IM injection, 100 units, Botox[®]</p> <p>Allergan Australia Pty Ltd</p> <p>Major submission</p>	<p>Hyperhidrosis (treats excessive sweating)</p>	<p>Extend the current Section 100 (Botulinum Toxin Program) listing to include: <u>Option 1:</u> severe primary axillary hyperhidrosis in adult and adolescent patients (> 12 years of age) who meet certain criteria and have failed or are intolerant to topical aluminium chloride hexahydrate. <u>Option 2:</u> treatment of severe primary axillary hyperhidrosis as per Option 1 but includes a measure of spontaneous resting axillary sweat production in the listing criteria.</p>	<p>The PBAC rejected the submission on the basis of a high and uncertain cost-effectiveness ratio.</p>
		<p>Sponsor's comments:</p>	<p>Allergan will continue to work with the PBAC to make the product available for this patient population.</p>
<p>Everolimus, tablets, 5 mg and 10 mg, Afinitor[®]</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Authority Required listing for treatment, as the sole PBS-subsidised therapy, of a patient with Stage IV clear cell variant renal carcinoma after failure of treatment with sorafenib or sunitinib.</p>	<p>Although the PBAC considered there was a clinical need for everolimus, the submission was rejected on the basis of uncertain clinical benefit and a high and uncertain cost-effectiveness ratio.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor will be considering its position regarding any future course of action.</p>

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<p>Ezetimibe, tablet 10 mg, Ezetrol[®]</p> <p>Ezetimibe with simvastatin, tablets, 10 mg-10 mg, 10 mg-20 mg, 10 mg-40 mg and 10 mg-80 mg, Vytorin[®]</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Minor submission</p>	<p>Lipid lowering drug</p>	<p>Change the current Authority Required (STREAMLINED) listings to Restricted Benefit.</p>	<p>The submission was rejected as the PBAC considered the more restrictive classification remained appropriate for these products.</p>
		<p>Sponsor's comments:</p>	<p>The Sponsor has no comment.</p>
<p>Intravenous Solutions</p> <p>Glucose, I.V. infusion, 69.5 mmol (anhydrous) per 250 mL (5%), 250 mL,</p> <p>Sodium chloride, I.V. infusion, 38.5 mmol per 250 mL (0.9%), 250 mL,</p> <p>Pharmatel Fresenius Kabi Pty Ltd.</p> <p>Minor submission</p>	<p>Parenteral Nutrition</p> <p>Electrolyte replacement</p>	<p>Unrestricted listing in the Dental section of the Schedule.</p>	<p>The PBAC did not recommend the addition of these products to the Dental Schedule on the grounds of a lack of demonstrated clinical need. Listing has proceeded as an unrestricted pharmaceutical benefit under the General Schedule.</p>
		<p>Sponsor's comments:</p>	<p>The Sponsor has no comment.</p>
<p>Imatinib, tablets, 100 mg and 400 mg (as mesylate), Glivec[®]</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Extend the current Authority Required listing to include adjuvant treatment of a patient at high risk of recurrence following complete resection of primary gastrointestinal stromal tumour who meets certain criteria.</p>	<p>The PBAC rejected the submission on the basis of uncertain clinical benefit and a high and highly uncertain cost-effectiveness ratio.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor will be considering its position regarding any future course of action.</p>
<p>Milk powder - nutrient rich, infant formula powder, 400 g, S-26 Gold Premgro[®]</p>	<p>Medicinal food</p>	<p>Option 1: Authority Required listing for treatment of premature infants born at less than 30 weeks gestation, up to the age of 6</p>	<p>The PBAC rejected the submission on the basis of limited evidence of long-term clinical benefit and unknown cost-</p>

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<p>Wyeth Australia Pty Ltd</p> <p>Minor submission</p>		<p>months for whom breast-feeding is not possible.</p> <p>Option 2: As above but for premature infants born at less than 33 weeks gestation.</p>	<p>effectiveness.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>
<p>Omalizumab (rch), powder for injection, 150 mg, Xolair[®].</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission.</p>	<p>Anti-asthma drug</p>	<p>Option 1: Section 100 (Highly Specialised Drugs Program) Public and private hospital authority required listing for initial and continuing treatment of uncontrolled severe allergic asthma despite optimised asthma therapy (OAT) in a patient who satisfies certain criteria.</p> <p>Option 2: As per option 1 but without oral corticosteroids (OCS) as part of optimised asthma therapy.</p>	<p>Although the PBAC considered there was a clinical need for omalizumab, the submission was rejected on the basis of uncertainty in the restrictions, uncertain clinical benefit and a high and unacceptable cost-effectiveness ratio.</p>
		<p>Sponsor's comments:</p>	<p>Novartis is disappointed that the PBAC has rejected the application to list omalizumab on the PBS, but is committed to working with the PBAC to address the issues of concern.</p>

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<p>Quetiapine fumarate, tablets, 100 mg, 200 mg and 300 mg (base), Seroquel[®]</p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>	<p>Bipolar disorder</p>	<p>Extend the current Authority Required (Streamlined) listing to include treatment, for up to 6 months, of an episode of acute mania associated with bipolar 1 disorder, in combination with lithium or sodium valproate.</p>	<p>The PBAC considered that this proposal should not have been submitted and evaluated as a minor submission. The PBAC rejected the submission on the basis of considerable uncertainty about the comparison with risperidone and has recommended the data be re-submitted in the form of a major submission to allow full evaluation of the issues identified.</p>
		<p>Sponsor's comments:</p>	<p>The Sponsor has no comment.</p>
<p>Quetiapine fumarate, tablets, 100 mg, 200 mg and 300 mg (base), Seroquel[®]</p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>	<p>Bipolar disorder</p>	<p>Extend the current Authority Required (Streamlined) listing to include maintenance treatment of bipolar 1 disorder, as monotherapy.</p>	<p>The PBAC considered that this proposal should not have been submitted and evaluated as a minor submission. The PBAC rejected the submission on the basis of considerable uncertainty about the comparison with olanzapine and has recommended the data be re-submitted in the form of a major submission to allow full evaluation of the issues identified.</p>
		<p>Sponsor's comments:</p>	<p>The Sponsor has no comment.</p>