

**JULY 2011 PBAC MEETING OUTCOMES - Deferrals**

<b>DRUG AND FORM</b>	<b>DRUG USE AND TYPE</b>	<b>LISTING REQUESTED BY SPONSOR</b>	<b>PBAC OUTCOME AND COMMENTS</b>
<p>ABATACEPT (rch), powder for I.V. infusion, 250mg, Orencia®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Major submission</p>	<p>Juvenile arthritis</p>	<p>Extend the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include the treatment of severe active juvenile idiopathic arthritis (JIA) in patients who have severe intolerance of, or toxicity due to, methotrexate or who have failed to achieve an adequate response to methotrexate.</p>	<p>The PBAC deferred its decision pending further discussion with the sponsor regarding the clinical trial data, administration costs and price.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>
<p>ALGLUCOSIDASE alfa-rch, powder for I.V. infusion, 50 mg, Myozyme®</p> <p>Genzyme Australasia Pty Ltd</p> <p>Major submission</p>	<p>Pompe disease</p>	<p>Section 100 (Highly Specialised Drugs Program) listing or inclusion on the Life Saving Drugs Program (LSDP) for the treatment of patients with late-onset Pompe disease.</p>	<p>The PBAC deferred its decision to seek further analysis of observational data provided to see if it will allow PBAC to have confidence that criterion 4 of the LSDP guidelines has been met.</p>
		<p>Sponsor's comments:</p>	<p>Genzyme is disappointed at the PBAC deferring its recommendation on Myozyme for late-onset Pompe disease, given the new evidence provided in the submission. Genzyme Australasia remains committed to working with the PBAC and the LSDP to ensure that people with late-onset Pompe disease have funded access to alglucosidase alfa</p>
<p>LINAGLIPTIN, tablet, 5 mg, Ondefo®/Trajenta®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Major submission</p>	<p>Type 2 diabetes</p>	<p>Authority required (Streamlined) listing for treatment of patients with type 2 diabetes in combination with metformin or a sulfonylurea.</p>	<p>The PBAC was of a mind to recommend listing of linagliptin on a cost minimisation basis compared with sitagliptin. However, in the absence of a decision by the TGA Delegate on the registration of linagliptin, the PBAC deferred a final recommendation. The PBAC agreed to finalise its decision on the listing of linagliptin following the receipt of a positive TGA Delegate's Summary.</p> <p>On the basis of the clinical data, the equi-effective doses are estimated as linagliptin 5mg daily and sitagliptin 100mg daily.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>

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<p>NEVIRAPINE, tablet 400 mg (extended release), Viramune XR<sup>®</sup></p> <p>Boehringer-Ingelheim Pty Ltd</p> <p>Minor submission</p>	<p>Anti-viral for HIV</p>	<p>Section 100 (Highly Specialised Drugs Program) Authority required listing of an extended-release form for treatment of HIV infection in combination with other antiretroviral agents.</p>	<p>The PBAC was concerned with implementation issues, particularly the requirement for new patients to be initiated on non-PBS listed starter packs. The PBAC deferred making a recommendation to seek further clarification from the sponsor on how the provision of the starter packs could be made binding and on whether a 14 tablet starter pack is currently available and could be TGA registered.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>
<p>NICOTINE, transdermal patch, releasing approximately 14 mg per 24 hours, Nicotinell Step 2<sup>®</sup>; releasing approximately 7 mg per 24 hours, Nicotinell Step 3<sup>®</sup></p> <p>Novartis Consumer Health Australasia Pty Ltd</p> <p>Minor submission</p>	<p>Smoking cessation</p>	<p>Authority required listing of two additional (lower) strengths of nicotine patch.</p>	<p>The PBAC deferred the submission to seek further advice from the Department and Medicare Australia on the best way of implementing the listing whilst still limiting nicotine treatment to a maximum of 12 weeks of PBS-subsidised nicotine therapy and allowing prescribers the flexibility to initiate therapy at any strength patch.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>