

MARCH 2012 PBAC MEETING OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>Boceprevir, capsule, 200 mg, Victrelis[®]</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Hepatitis C</p>	<p>Re-submission for Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (STREAMLINED) listing for treatment of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who are treatment naïve or who have failed one prior attempt with interferon alfa or peginterferon alfa treatment for hepatitis C and who meet certain criteria.</p>	<p>The PBAC deferred its decision pending further negotiation with the sponsor as the cost effectiveness ratio remained unacceptably high and uncertain.</p>
		<p>Sponsor's comments:</p>	<p>Merck Sharp & Dohme is committed to ensuring that Genotype 1 hepatitis C patients get access to boceprevir as soon as possible. Merck Sharp & Dohme is working with the PBAC to ensure that a recommendation can be made at the earliest opportunity.</p>
<p>Pitavastatin, tablet, 1 mg, 2 mg and 4 mg (as calcium), Livalo[®]</p> <p>Abbott Australasia Pty Ltd</p> <p>Major submission</p>	<p>Lipid lowering drug</p>	<p>Restricted Benefit listing for use in patients who meet the criteria set out in the General Statement for Lipid Lowering Drugs.</p>	<p>The PBAC deferred making a recommendation to the Minister on the suitability for PBS subsidy of pitavastatin. The PBAC requested that the pitavastatin submission be brought back to it for reconsideration alongside the Statins Review at its July 2012 meeting.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comments.</p>

MARCH 2012 PBAC MEETING OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>Sunitinib, capsule, 12.5 mg, 25 mg and 50 mg (as malate), Sutent[®]</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Re-submission for an extension to the current Authority Required listing to include the initial and continuing treatment of metastatic, unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (or carcinoma) (pancreatic NET) in a patient who is symptomatic (despite somatostatin analogues) or has documented disease progression.</p>	<p>The PBAC deferred its decision pending further negotiation with the sponsor as the cost-effectiveness ratio of sunitinib for this indication was unacceptably high.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comments.</p>
<p>Telaprevir, tablet, 375 mg, Incivo[®]</p> <p>Janssen-Cilag Pty Ltd</p> <p>Major submission</p>	<p>Hepatitis C</p>	<p>Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (STREAMLINED) listings for the treatment, in combination with peginterferon-alfa and ribavirin, of chronic genotype 1 hepatitis C in a treatment naïve patient 18 years or older who has compensated liver disease and meets certain criteria.</p>	<p>The PBAC deferred its decision pending further negotiation with the sponsor as the cost effectiveness ratio was highly uncertain.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comments.</p>