

NOVEMBER 2012 PBAC MEETING OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENT
<p>EVEROLIMUS, tablets, 2.5 mg, 5 mg and 10 mg, Afinitor[®]</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Subependymal giant cell astrocytoma (SEGA)</p>	<p>Authority Required listing for the initial and continuing treatment of SEGA associated with tuberous sclerosis in a patient who meets certain criteria.</p>	<p>The PBAC deferred making a recommendation as a cost-effectiveness ratio could not be determined due to insufficient trial data from small patient numbers. The PBAC considered discussion with the sponsor about listing through a managed entry scheme to be a potential way forward, in the context of a high clinical need and uncertain clinical efficacy.</p>
		<p>Sponsor's comments</p>	<p>Novartis welcomes the opportunity to work with the PBAC to explore a way forward to provide access to everolimus for these patients.</p>
<p>FOLIC ACID, tablet, 500 micrograms, Foltabs[®]</p> <p>Petrus Pharmaceuticals Pty Ltd</p> <p>Minor submission</p>	<p>Folic acid supplement</p>	<p>Unrestricted benefit listing.</p>	<p>The PBAC deferred making a recommendation to seek advice on the current usage of folic acid on the PBS, in particular in vulnerable patient groups such as the Aboriginal and Torres Strait Islander population.</p>
		<p>Sponsor's comments</p>	<p>The sponsor has no comment.</p>

<p>MARAVIROC, tablets, 150 mg and 300 mg, Celcentri®</p> <p>GlaxoSmithKline on behalf of ViiV Healthcare</p> <p>Major submission</p>	<p>HIV infection</p>	<p>Extend the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include first line treatment, in combination with other antiretroviral agents, of a patient with CCR5-tropic HIV-1 infection, who meets certain criteria.</p>	<p>The PBAC deferred making a recommendation to seek relevant advice from the Medical Services Advisory Committee (MSAC), and to hold discussions with the sponsor on the approach to the economic comparison.</p>
		<p>Sponsor's comments</p>	<p>The sponsor awaits further advice from MSAC and will respond to the PBAC with respect to the approach to the economic comparison.</p>
<p>RIBAVIRIN and PEGINTERFERON ALFA-2A, pack containing 168 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 135 micrograms, pack containing 112 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 180 micrograms, pack containing 140 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 180 micrograms, pack containing 168 tablets ribavirin 200 mg and 4 pre-filled pens peginterferon alfa-2a 180 micrograms, Pegasys RBV®</p> <p>Roche Products Pty Ltd</p> <p>Minor submission</p>	<p>Chronic hepatitis C</p>	<p>Authority Required listing of packs containing ribavirin tablets and peginterferon alfa-2a pre-filled pens for the same chronic hepatitis C indications as for the current Pegasys RBV combination packs that contain ribavirin tablets and peginterferon alfa-2a pre-filled syringes.</p>	<p>The PBAC deferred making a recommendation to seek further clarification on whether the new presentation can be marked as substitutable with existing pre-filled syringe packs.</p>
		<p>Sponsor's comments</p>	<p>The sponsor needs to clarify the decision with the PBAC.</p>
<p>RIFAXIMIN, tablet, 550 mg, Xifaxan®</p> <p>Norgine Pty Ltd</p> <p>Minor submission</p>	<p>Liver disease</p>	<p>Restricted Benefit listing for the prevention of hepatic encephalopathy in adult patients meeting certain criteria</p>	<p>The PBAC deferred making a recommendation to seek further advice on the development of antimicrobial resistance and further information from the sponsor in relation to a proposed managed entry scheme listing.</p>

		Sponsor's comments	Norgine looks forward to working with PBAC to provide the necessary information in a timely manner to facilitate a recommendation for approval.
TRASTUZUMAB, powder for I.V. infusion, 60 mg and 150 mg, Herceptin® Roche Products Pty Ltd Major submission	Stomach and gastrointestinal cancer	Extend the current Section 100 (Efficient Funding of Chemotherapy) Authority Required listing to include the treatment of HER2 positive, advanced (equivalent stage III or IV) adenocarcinoma of the stomach or gastro oesophageal junction, in patients who have not received prior treatment for advanced disease, in combination with cisplatin and either capecitabine or 5 fluorouracil, with a WHO performance status of 2 or less and who does not have progressive disease.	The PBAC deferred making a recommendation to seek further Medical Services Advisory Committee (MSAC) advice on resolution of testing issues and to further clarify with the sponsor the approach on the cost-effectiveness analyses (across the MSAC-supported scenarios and including the ToGA ITT scenario) and proposed risk share arrangement.
		Sponsor's comments	Roche is committed to ensuring that patients with advanced HER2 positive gastric cancer have access to trastuzumab and is working with the PBAC and MSAC to ensure that a recommendation can be made.