July 2013 PBAC Meeting Outcomes - "1st time" decisions not to recommend

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Recommendation
Afatanib, tablets, 20 mg, 30 mg, 40 mg and 50 mg, Giotrif®/Tomtovok®: Boehringer Ingelheim Pty Ltd Major submission	Lung cancer	Authority required listing for locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer as second or third line therapy.	The PBAC rejected the submission on the basis that the requested afatinib listing is outside its proposed TGA indication and that the evidence provided in the submission did not support the proposed afatinib listing in the submission.
		Sponsor's comments:	Sponsor had no comments
Aflibercept, solution for intravitreal injection, 40 mg per mL, Eylea® Bayer Australia Limited Major submission	Vision loss	Extend the current Authority required listing to include sole subsidised treatment of patients with macular oedema caused by central retinal vein occlusion (CRVO).	The PBAC rejected the submission on the basis of an unacceptably high and likely underestimated ICER for aflibercept compared with best supportive care, and, on the basis of inadequate comparative data against either bevacizumab or ranibizumab in the treatment of macular oedema due to CRVO.
		Sponsor's comments:	The sponsor had no comment
Aflibercept, solution for I.V. administration, 100 mg per 4 mL and 200 mg per 8 mL, Zaltrap® Sanofi-Aventis Australia Pty Ltd Major Submission	Bowel cancer	Authority required (Streamlined) listing for treatment, in combination with an irinotecan-fluoropyrimidine-based chemotherapy, of a patient with previous treatment with an oxaliplatin-based chemotherapy regimen for metastatic colorectal cancer with a WHO performance status of 0 or 1.	The PBAC rejected the submission on the basis of inadequate comparative efficacy and potentially worse safety resulting in an unacceptably high ICER, a lack of clarity regarding the clinical place in therapy of aflibercept, an absence of comparative data against other relevant chemotherapy regimens, and, on the basis that non-inferiority against cetuximab had not been adequately established.

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		Sponsor's comments:	The sponsor is disappointed by the PBAC's decision and, whilst appreciating the Committee's concerns about the high ICER, believes that Zaltrap does provide clinically meaningful benefits for survival and response rates compared to other regimens used in the treatment of metastatic colorectal cancer (mCRC), and with a manageable safety profile. The sponsor remains committed to enabling access to Zaltrap for mCRC patients.
Collagenase clostridium histolyticum, injection, 0.9 mg per vial, Xiaflex® Actelion Pharmaceuticals Australia Pty Ltd Major Submission	Dupuytren's contracture	Authority required listing for treatment of Dupuytren's contracture for patients who are unable to simultaneously place the affected finger and palm flat on a table due to a Dupuytren's contracture with a palpable cord.	The PBAC rejected the submission on the basis of the clinical evidence, which inadequately supports the claim of noninferior efficacy against surgical fasciectomy and an unacceptably high price of collagenase clostridium histolyticum (CCH).
		Sponsor's comments:	The sponsor has no comment.
Eltrombopag olamine, tablets, 25 mg, 50 mg, 75 mg and 100 mg*, Revolade® GlaxoSmithKline Australia Pty Ltd Major submission Note: 100 mg not assessed in this	Decreased platelet count	Extend the current Section 100 listing to include treatment of thrombocytopenia in patient with documented chronic hepatitis C virus.	The PBAC rejected the submission to extend the PBS-listing of eltrombopag due to issues with the nominated comparator which subsequently impacted the clinical evidence and economic evaluation.
		Sponsor's comments:	The sponsor will be considering its position regarding any future courses of action.

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application			
Lisdexamfetamine dimesilate, capsules, 30 mg, 50 mg, and 70 mg, Vyvanse® Shire Australia Pty Ltd Major submission	Attention Deficit Hyperactivity Disorder (ADHD)	Authority required listing for treatment of ADHD in a patient diagnosed between the ages of 6 and 18 years who requires continuous coverage over 13 hours.	The PBAC rejected the submission for lisdexamfetamine on the basis of insufficient clinical evidence to support claims of superiority in comparative effectiveness, non-inferiority in comparative safety and unacceptable cost-effectiveness compared with methylphenidate OROS.
		Sponsor's comments:	Shire will continue to work with the PBAC to ensure that patients with ADHD have access to an alternative long acting medicine on the PBS.
Nabiximols, oromucosal spray, 27 mg per mL tetrahydrocannabinol and 25 mg per mL cannabidiol, 3x10 mL, Sativex® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Multiple sclerosis	Authority required listing for management of severe spasticity due to multiple sclerosis in adult patients who are intolerant to anti-spasticity medication and/or have not adequately responded to anti-spasticity medication.	The PBAC rejected the submission on the basis of insufficient evidence to establish comparative effectiveness and safety compared with standard care alone in patients who are intolerant to anti-spasticity medication; and no evidence of efficacy and safety provided in comparison with high dose baclofen alone, or in combination with dantrolene or diazepam as the second-line therapy.
		Sponsor's comments:	Novartis is disappointed with the PBAC decision but remains committed to ensuring MS patients can access Sativex for spasticity.

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Potassium iodate, tablet, 253 mcg equivalent to 150 mcg iodine, NeuroTabs® AFT Pharmaceuticals Pty Ltd Minor submission	Iodine deficiency	Restricted benefit listing for iodine supplementation for pregnant and lactating women at risk of developing iodine deficiency	The PBAC rejected the submission on the basis of inadequate comparative data and a lack of an economic comparison against existing non-prescription iodine containing supplements.
		Sponsor's comments:	The sponsor has no comment
Ruxolitinib, tablet, 5 mg, 15 mg and 20 mg, Jakavi® Novartis Pharmaceuticals Australia Pty Ltd Major Submission	Bone marrow disorder	Authority Required listing for treatment of disease-related symptoms in patients with intermediate or high-risk primary (idiopathic) myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.	The PBAC rejected the submission requesting PBS listing of ruxolitinib for treatment of myelofibrosis on the basis of a high and unacceptable ICER.
		Sponsor's comments:	Novartis will work with the PBAC to make Jakavi available for patients with myelofibrosis.
Tocilizumab, injection, 80 mg per 4 ml, 200 mg per 10 mL and 400 mg per 20 mL, Actemra® Roche Products Pty Limited Major submission	Rheumatoid arthritis	Change to the NOTE in the restriction for the Authority required listing for severe rheumatoid arthritis where a patient has had an inadequate response to disease modifying anti rheumatic drugs (DMARDs), (including methotrexate), and/or where a patient cannot tolerate 7.5 mg of methotrexate weekly.	The PBAC rejected the sponsor's suggested change to the NOTE. The PBAC considered that the current PBS restriction already permits the use of tocilizumab monotherapy where the patient has a contraindication or intolerance to methotrexate. The PBAC therefore recommended that the following section of the NOTE be deleted: 'PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in

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			combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.'
		Sponsor's comments:	Roche is pleased that the PBAC accepted that tocilizumab monotherapy is non-inferior to tocilizumab with methotrexate, and welcomes the removal of the NOTE in the restriction to increase the clarity for the prescriber in the appropriate use of monotherapy.
Trastuzumab emtansine, powder for I.V. infusion, 100 mg and 160 mg, Kadcyla® Roche Products Pty Limited Major submission	Breast cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for treatment of a patient with HER2-positive unresectable locally advanced or metastatic breast cancer who has received prior therapy with trastuzumab (Herceptin®) and a taxane and whose disease has progressed despite treatment with trastuzumab for metastatic disease or within 6 months of completing adjuvant therapy.	The PBAC rejected the submission on the basis of incorrect comparator. The PBAC considered that the correct comparator is lapatinib+capecitabine, and noted that the ICER against this regimen is unacceptably high.
		Sponsor's comments:	The sponsor had no comment

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Vildagliptin, tablet, 50 mg, Galvus® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Type 2 diabetes	Authority required (Streamlined) listing for patients with type 2 diabetes in triple combination therapy with metformin and a sulfonylurea.	The PBAC rejected the listing of viladagliptin 50 mg tablet in triple therapy on the PBS due to the inappropriate comparator. The PBAC did not accept pioglitazone as the appropriate comparator in view of concerns about adverse cardiovascular events and its diminishing use in the clinical treatment algorithm for type 2 diabetes.
		Sponsor's comments:	Novartis is disappointed with the PBAC decision and will be considering its position regarding any future course of action.
Vildagliptin with metformin, tablets, 50 mg-500 mg, 500 mg-850 mg and 50 mg-1000 mg, Galvumet® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Type 2 diabetes	Authority required (Streamlined) listing for patients with type 2 diabetes in combination with a sulfonylurea (i.e. triple combination therapy).	The PBAC rejected the listing of vildagliptin/metformin FDC with a sulfonylurea because the cost-minimisation analysis was contingent on the PBAC accepting bioequivalence as a surrogate for efficacy/safety in triple therapy, and that the effectiveness of vildagliptin in triple therapy would apply to the FDC. The PBAC considered that since no evidence was presented to inform the efficacy/safety of vildagliptin/metformin FDC in triple therapy, it was unclear whether the cost minimisation analysis was appropriate.
		Sponsor's comments:	Novartis is disappointed with the PBAC decision and will be considering its position regarding any future course of action.