

MARCH 2008 PBAC OUTCOMES - "1st time" Decisions not to Recommend

| DRUG AND FORM | DRUG USE AND TYPE | LISTING REQUESTED BY SPONSOR | PBAC OUTCOME AND COMMENTS |
|---|----------------------|--|---|
| <p>ALENDRONATE SODIUM, tablet equivalent to 70 mg alendronic acid, Fosamax Once Weekly[®], ALENDRONATE SODIUM with COLECALCIFEROL tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol, Fosamax Plus[®] Merck Sharp & Dohme (Australia) Pty Limited</p> <p>Major submission</p> | <p>Osteoporosis</p> | <p>Authority Required – <i>treatment of patients aged 70 years of age or older and with a BMD (Bone Mineral Density) T-score ≤ -2.5.</i></p> | <p>The PBAC rejected the application because of concerns of a less favourable ratio of harms to benefits in this wider population and an unacceptable cost-effectiveness ratio</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor disagrees with this assessment and is working with the PBAC to resolve the issues.</p> |
| <p>APREPITANT, pack containing 1 capsule 125 mg and 2 capsules 80 mg, Emend[®] Merck Sharp and Dohme (Australia) Pty Ltd</p> <p>Minor submission</p> | <p>Anti-nauseant</p> | <p>Request to amend current authority required restriction <i>to expand PBS access to include patients at a high risk of chemotherapy induced emesis.</i></p> | <p>The PBAC rejected the application because of the lack of data to support the cost-effectiveness of use in this expanded population.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor intends to clarify the decision with the PBAC and will be considering its position regarding any future course of action.</p> |
| <p>APREPITANT, capsules, 80 mg, Emend Duo Pack[®] and FOSAPREPITANT DIMEGLUMINE, powder for I.V. infusion, 115 mg (base), Emend IV[®] Merck Sharp and Dohme (Australia) Pty Ltd</p> | <p>Anti-nauseant</p> | <p>Seeking authority required listing of a new formulation <i>for the management of nausea and vomiting associated with cytotoxic chemotherapy in patients who meet certain criteria</i></p> | <p>The PBAC rejected this submission as it considered that the clinical need for an intravenous form of aprepitant (fosaprepitant) low, and the requirement for patients to make an additional co-payment should this listing proceed (as two scripts would be required for the two different dosage forms) was inappropriate</p> |

| | | | |
|---|----------------------------|--|---|
| Minor submission | | | in the absence of any evidence of increased benefit. |
| | | Sponsor's comments | The sponsor understands the PBAC decision and intends to make this formulation available for patients on the private market. |
| BEVACIZUMAB, solution for IV infusion, 100 mg in 4 mL and 400 mg in 16 mL, Avastin® Roche Products Pty Limited Major submission | Colo-rectal cancer | Section 100 Special Authority Program - <i>for the treatment of metastatic colorectal cancer in previously untreated patients with a WHO performance status of 0 or 1 in combination with 5FU & folinic acid or irinotecan, 5FU & folinic acid, and treatment in combination with chemotherapy where disease progression has occurred following first line treatment which includes bevacizumab.</i> | The PBAC rejected the submission on the grounds of a high cost effectiveness ratio in the first line population and high and uncertain cost-effectiveness in the second line population. |
| | | Sponsor's comments | The sponsor will be considering its position regarding any future course of action. |
| FENOFIBRATE, tablets, 48 mg and 145 mg, Lipidil®, Laboratoires Fournier S.A Minor submission | Cholesterol lowering agent | To seek an addition to the current NOTE in the restriction | The PBAC considered that there was insufficient reason to amend the current PBS entry for fenofibrate and that the requested change did not inform about the safety or otherwise of using the combination, since it is unknown whether the basis for the increased risk of myositis, etc is kinetic or pharmacodynamic. |

| | | | |
|--|-------------------------------|--|---|
| | | Sponsor's comments | The sponsor had no comment |
| <p>GEFITINIB, tablet, 250 mg, Iressa[®], AstraZeneca Pty Ltd</p> <p>Minor submission</p> | Lung cancer | Request to amend the current restriction for gefitinib by removal of the requirement for the activating EGFR mutation; and alignment of the restriction with the recently amended TGA indication. | The PBAC considered that at this time, there is inadequate evidence available to allow an assessment to be made on the cost-effectiveness of gefitinib in the population that would be covered under the requested listing and that more detailed information regarding new clinical data are required. |
| | | Sponsor's comments | AstraZeneca had no comment. |
| <p>IBANDRONIC ACID, tablet, 50 mg, Bondronat[®], Hospira Australia Pty Ltd</p> <p>Major submission</p> | Bone pain in cancer patients. | Restricted benefit. | The PBAC rejected the submission because of inadequate evidence that ibandronic acid is not inferior to the comparator, clodronate. |
| | | Sponsor's comments | The sponsor will be considering its position regarding any future course of action. |
| <p>LENALIDOMIDE, capsules, 5 mg, 10 mg, 15 mg and 25 mg, Revlimid[®], Celgene Pty Ltd</p> <p>Major submission</p> | Multiple myeloma | Section 100 Private hospital authority required listing <i>for relapsed/refractory multiple myeloma in combination with dexamethasone in a patient who has undergone at least one other therapy.</i> | The PBAC rejected the application on the basis of the quality of the comparative data, the uncertainty of the clinical claim and the resulting high and uncertain cost effectiveness ratios. |

| | | | |
|---|---------------------|--|---|
| | | Sponsor's comments | Celgene is committed to working with the PBAC to address any areas of uncertainty and ensure that patients are able to access lenalidomide through the PBS. |
| <p>LEVODOPA WITH CARBIDOPA, intestinal gel, 20 - 5 mg per mL, Duodopa[®], Solvay Pharmaceuticals</p> <p>Major submission</p> | Parkinson's disease | <p>Section 100 public and private hospital authority required listing <i>for treatment by a neurologist of patients with advanced Parkinson's disease with severe disabling motor fluctuations not adequately controlled by oral therapy.</i></p> | <p>The PBAC rejected the submission on the basis of the high and highly uncertain incremental cost effectiveness ratio for levodopa with carbidopa gel compared to standard medical management.</p> |
| | | Sponsor's comments | <p>Solvay will work with the PBAC to address all the issues identified in the Duodopa PBAC submission. Solvay strongly believes that the cost effectiveness analysis should include all the costs associated with Parkinson disease, for example, carer burden.</p> |
| <p>MIGLUSTAT, capsule, 100 mg, Zavesca[®], Actelion Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p> | Gaucher Disease | <p>Authority required <i>for patients who qualify for treatment with Enzyme Replacement Therapy (ERT) under the Life Saving Drugs Program who cannot be or have not been treated successfully with ERT according to the treatment physician.</i></p> | <p>The PBAC rejected the application on the basis of unacceptably high cost-effectiveness. However, the Committee indicated that the use of miglustat for the treatment of Gaucher Disease meets the criteria for the Life Saving Drugs Program (LSDP).</p> |
| | | Sponsor's comments | <p>The sponsor agrees that Zavesca is an appropriate drug to be listed under the Life Savings Drug Program.</p> |

| | | | |
|--|-----------------------------------|---|--|
| <p>MOMETASONE FUROATE, cream, 1 mg per g (0.1%), ointment, 1 mg per g (0.1%), 30 g and 45 g Elocon[®], Schering-Plough Pty Limited.</p> <p>Minor submission</p> | <p>Topical corticosteroid</p> | <p>Restricted benefit listing of larger pack sizes for widespread corticosteroid responsive dermatoses.</p> | <p>The PBAC rejected the application as it remained concerned, as previously, that a larger maximum quantity would result in more wastage and might inadvertently lead to higher usage by some patients with associated safety issues. The PBAC noted that patients with widespread dermatoses are catered for under the current authority approval arrangement.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor had no comment.</p> |
| <p>OXYBUTYNIN, 3.9 mg/day transdermal patch, Oxytrol[®], Hospira Australia Pty Ltd</p> <p>Major submission</p> | <p>Incontinence</p> | <p>Restricted benefit.</p> | <p>The PBAC rejected the submission based on uncertainty regarding the population that would use the transdermal patch, the applicability of the results from the clinical trials, uncertain clinical benefit, and uncertain cost effectiveness.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor will be considering its position regarding any future course of action.</p> |
| <p>PEGFILGRASTIM, injection, 6 mg in 0.6mL pre-filled syringe, Neulasta[®], Amgen Australia Pty Ltd</p> <p>Major submission</p> | <p>Prevention of neutropenia.</p> | <p>Section 100 Private hospital authority required</p> | <p>The PBAC rejected an extension to listing on the basis of uncertain clinical benefit and uncertain cost-effectiveness in the broader patient group.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor will continue to work with the PBAC to reach a satisfactory outcome.</p> |

| | | | |
|--|----------------------------|---|--|
| <p>QUETIAPINE FUMARATE, modified release tablets, 50 mg, 200 mg, 300 mg and 400 mg, Seroquel XR[®] AstraZeneca Pty Ltd</p> <p>Minor submission</p> | <p>Anti-psychotic</p> | <p>Authority required (streamlined) listing <i>for schizophrenia</i></p> | <p>The PBAC rejected the application on the basis of the potential for confusion due to the different formulations and different indications compared with the immediate release formulations.</p> |
| | | <p>Sponsor's comments</p> | <p>AstraZeneca is working toward making Seroquel XR available as quickly as possible.</p> |
| <p>ROTIGOTINE, transdermal patch, 4.5 mg (releasing approximately 2 mg per 24 hours), 9.0 mg (releasing approximately 4 mg per 24 hours), 13.5 mg (releasing approximately 6 mg per 24 hours), 18.0 mg (releasing approximately 8 mg per 24 hours), Neupro[®] UCB Australia Pty Ltd</p> <p>Major submission</p> | <p>Parkinson's disease</p> | <p>Unrestricted listing</p> | <p>The PBAC rejected the application on the grounds a comparison should have been made against levodopa and a decarboxylase inhibitor in early Parkinson's disease, insufficient evidence of the claim of superior safety profile over cabergoline, and unacceptable cost offsets.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor looks forward to working with the PBAC to clarify the decision and progress these matters towards a successful resolution.</p> |
| <p>SUNITINIB MALATE, capsules, 12.5 mg, 25 mg and 50 mg, Sutent[®] Pfizer Australia</p> <p>Major submission</p> | <p>Anti Cancer drug</p> | <p>Authority required <i>for the treatment of advanced/metastatic renal cell carcinoma (RCC) in patients with an ECOG performance status of 0 or 1.</i></p> | <p>The PBAC rejected the submission, based on high and uncertain cost effectiveness ratios.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor notes the PBAC's view that the cost-effectiveness ratio is too high and will consider its position regarding any future course of action.</p> |

| | | | |
|---|--------------------------|---|--|
| <p>SUNITINIB MALATE, capsules, 12.5 mg, 25 mg and 50 mg, Sutent[®] Pfizer Australia Pty Ltd</p> <p>Major submission</p> | <p>Anti Cancer drug</p> | <p>Section 100 Authority required <i>for the treatment of gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate due to resistance or intolerance.</i></p> | <p>The PBAC rejected the submission due to a high and uncertain incremental cost effectiveness ratio, mainly due to the impact of continued sunitinib post-progression.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor notes the PBAC's view that the cost-effectiveness ratio is too high and will consider its position regarding any future course of action.</p> |
| <p>TAMSULOSIN, prolonged release tablet, 400 micrograms, Flomaxtra[®] CSL Biotherapies Limited</p> <p>Major submission</p> | <p>Enlarged prostate</p> | <p>Unrestricted listing <i>for relief of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).</i></p> | <p>The PBAC considered uncertainty was associated with interpretation of the trial data and the economic modelling, and therefore rejected the submission because of high and uncertain cost-effectiveness ratios.</p> |
| | | <p>Sponsor's comments</p> | <p>The sponsor need to clarify the decision with the PBAC.</p> |