NOVEMBER 2010 PBAC MEETING OUTCOMES - "1st time" decisions not to recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
Agomelatine, tablet, 25 mg, Valdoxan® Servier Laboratories (Australia) Pty Ltd Major submission	Anti-depressant	Restricted Benefit listing for major depressive disorders.	The PBAC rejected the submission because of uncertainty around the claim that agomelatine is superior to venlafaxine and the resultant uncertainty in the economic analysis.
		Sponsor's comments:	Servier is working with the PBAC and leading psychiatrists to ensure that agomelatine is PBS-listed as quickly as possible.
Aztreonam, powder for inhalation, 75 mg, with diluent, Cayston® Gilead Sciences Pty Ltd Major submission	Anti-infective for use in cystic fibrosis	Section 100 Highly Specialised Drugs Program listing for the control of gram-negative bacteria, particularly *P.aeruginosa* in the respiratory tract of patients with moderate to severe cystic fibrosis who meet certain criteria.	The PBAC rejected the submission on the basis of an unacceptably high and uncertain cost-effectiveness ratio.
		Sponsor's comments:	Gilead believes aztreonam meets an important therapeutic need for patients with cystic fibrosis and will continue to work with the PBAC to secure a PBS listing for aztreonam.
Bevacizumab, solution for I.V. infusion, 100 mg in 4 mL and 400 mg in 16 mL, Avastin® Roche Products Pty Ltd Major submission	Anti-cancer drug	Authority Required and Section 100 Chemotherapy Pharmaceutical Access Program listing for the treatment as monotherapy of relapsed or progressing glioblastoma multiforme.	The PBAC rejected the submission on the basis of uncertain clinical benefit and an unacceptably high and uncertain incremental cost-effectiveness ratio.
		Sponsor's comments:	The sponsor had no comment.

Budesonide with eformoterol fumarate dihydrate, oral pressurised inhalation, 200 micrograms – 6 micrograms per dose, Symbicort Rapihaler 200/6® AstraZeneca Pty Ltd Minor submission	Asthma and chronic obstructive pulmonary disease (COPD)	Restricted Benefit listing of a new form of a fixed dose combination product for the same indications as the current listed product, Symbicort Turbuhaler 400/12®, and for an extension to listing for the treatment of COPD sought in the major submission to this meeting.	The PBAC rejected the submission on the grounds that the inconsistencies between the maximum recommended doses for the Rapihaler and Turbuhaler delivery devices of Symbicort raise Quality Use of Medicines issues, including patient confusion, which must be resolved before a PBS listing for the Rapihaler device can be supported.
		Sponsor's comments:	AstraZeneca will continue to work towards PBS listing for Symbicort Rapihaler.
Corifollitropin alfa, solution for injection, 100 micrograms in 0.5 mL pre-filled syringe, 150 micrograms in 0.5 mL pre-filled syringe, Elonva® Schering-Plough Pty Ltd (Merck Sharp & Dohme) Major submission	Fertility drug	Section 100 IVF/GIFT Treatment Program listing for patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.	The PBAC rejected the submission on the basis of uncertainty about the claim that it is non-inferior in terms of comparative effectiveness and safety to follitropin beta, and the uncertainty in the cost-minimisation analysis resulting from this clinical uncertainty and from the pricing structure proposed by the sponsor.
		Sponsor's comments:	The sponsor believes that comparative efficacy and safety is demonstrated in the controlled clinical trials as accepted by the TGA. The sponsor will consult with clinical experts to document the clinical need for this product.

Dronedarone, tablet, 400 mg (as hydrochloride), Multaq® Sanofi-Aventis Australia Pty Ltd Major submission	Abnormal heart rhythm	Authority Required (Streamlined) listing for the treatment of paroxysmal or persistent atrial fibrillation or flutter in addition to standard therapy in patients with at least one additional cardiovascular risk factor.	The PBAC rejected the submission because of uncertainty about the extent of clinical benefit, if any, in terms of improved survival over the main comparator, amiodarone, and because of the resultant uncertainty in the economic analysis.
		Sponsor's comments:	Sanofi-Aventis is disappointed by the recommendation but it is committed to continuing to work with the PBAC to ensure that dronedarone is available on the PBS for people with atrial fibrillation.
Eltrombopag, tablets, 25 mg and 50 mg (as olamine), Revolade® GlaxoSmithKline Australia Pty Ltd Major submission	Idiopathic thrombocytopenia purpura – a bleeding disorder	Section 100 Highly Specialised Drugs Program listing for adult patients with chronic immune (idiopathic) thrombocytopenia meeting certain criteria.	The PBAC rejected the submission on the basis of uncertain clinical effectiveness in comparison with romiplostim.
		Sponsor's comments:	The sponsor is disappointed by the decision but is working with PBAC to address this uncertainty in order to make eltrombopag available to patients as soon as possible.
Gefitinib, tablet, 250 mg, Iressa® AstraZeneca Pty Ltd Major submission	Anti-cancer drug	Authority Required listing for the treatment of locally advanced or metastatic non-small cell lung cancer, as monotherapy, in patients with an activating mutation of the EGFR gene.	The PBAC rejected the submission on the basis of unacceptably high and uncertain cost-effectiveness.
		Sponsor's comments:	AstraZeneca will continue to work towards PBS listing of gefitinib for this patient group.

Indacaterol, capsule containing powder for oral inhalation, 150 micrograms and 300 micrograms (as maleate), Onbrez® Breezhaler® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Chronic obstructive pulmonary disease (COPD)	Restricted Benefit listing for the treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease.	The PBAC rejected the submission because of uncertainty about the clinical place of indacaterol in the treatment of COPD, because of concerns about the long-term safety of long acting beta agonist (LABA) without inhaled corticosteroid (ICS) therapy in COPD, and because the submission did not provide any data on the comparative efficacy and safety of indacaterol and LABA/ICS combinations, which the PBAC considered indacaterol would also replace in clinical practice.
		Sponsor's comments:	Novartis is committed to working with the PBAC to address its concerns in order to ensure successful reimbursement for indacaterol.
Liraglutide (rys), solution for injection, 3 mL pre-filled injection pen, 6 mg per mL, Victoza® Novo Nordisk Pharmaceuticals Pty Ltd	Type 2 diabetes	Authority Required (Streamlined) listing for type 2 diabetes mellitus patients as: 1) Combination therapy with metformin and a sulfonylurea (triple therapy) 2) Combination therapy with metformin or a sulfonylurea (dual therapy).	The PBAC rejected the submission because of an unacceptably high and uncertain cost-effectiveness ratio.
		Sponsor's comments:	Novo Nordisk is disappointed with the PBAC's recommendation. Novo Nordisk will however work constructively with the PBAC to ensure that liraglutide is made available for patients and physicians dealing with the burden of type 2 diabetes as soon as possible.

Omega-3-acid ethyl esters 90, soft capsule, 1,000 mg, Omacor® Abbott Products Pty Ltd Major submission	Prevention against further heart attacks	Restricted Benefit listing as adjuvant treatment in secondary prevention after myocardial infarction.	The PBAC rejected the submission on the basis of inadequate clinical data to establish efficacy in the proposed Australian population and therefore a highly uncertain cost-effectiveness ratio.
		Sponsor's comments:	The sponsor had no comment.
Oxybutynin, transdermal patch, 36 mg (releasing approximately 3.9 mg per 24 hours), Oxytrol® Hospira Australia Pty Ltd Minor submission	Urinary incontinence	The sponsor of oxybutynin requested that the recommended restriction for solifenacin be changed from "…can not tolerate oral oxybutynin" to "…can not tolerate oxybutynin".	The PBAC recommended no change to the wording of the current Restricted Benefit listing for solifenacin. The PBAC noted that the restriction recommended for solifenacin at the July 2010 meeting placed solifenacin as a second-line treatment along with oxybutynin patches for the treatment of patients who cannot tolerate oral oxybutynin. Therefore, the choice to use solifenacin oral tablets or transdermal oxybutynin is a clinical decision for the prescriber, and that the current restrictions for these two products allow this choice.
		Sponsor's comments:	The sponsor had no comment.
Plerixafor, solution for subcutaneous injection, 20 mg per mL, 1.2 mL, Mozobil® Genzyme Australasia Pty Ltd Major submission	Anti-cancer drug	Section 100 Highly Specialised Drugs Program listing for the treatment of patients with non-Hodgkin lymphoma, Hodgkin lymphoma and multiple myeloma meeting certain criteria.	The PBAC rejected the submission on the basis of an inappropriate comparator for the first-line indications, uncertain clinical benefit in the second-line setting relating to the lack of comparative data, and uncertainty regarding the economic model.
		Sponsor's comment:	Genzyme Australasia is committed to working to address the PBAC's concerns.