NOVEMBER 2011 PBAC MEETING OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
Icatibant, injection, 30 mg in 3 mL (as acetate), single use pre-filled syringe, Firazyr® Shire Australia Pty Ltd Minor submission	Acute hereditary angioedema	Resubmission for an Authority Required listing for the treatment of hereditary angioedema.	The PBAC deferred its decision pending further negotiation with the sponsor as the cost effectiveness ratio remained unacceptably high and uncertain
		Sponsor's comments:	Shire accepts that the PBAC recognises the high clinical need for Icatibant and welcomed the opportunity to negotiate a lower price and a suitable risk sharing agreement. Shire however is disappointed that there is no procedure for negotiation of a listing to occur following a PBAC deferral in the absence of a new (minor) submission.
Mycophenolate sodium, tablets (enteric coated), 180 mg and 360 mg (mycophenolic acid), Myfortic® Novartis Pharmaceuticals Major submission	Lupus nephritis	Extend the current Section 100 and Section 85 Authority Required listings to include the treatment, initiated by a nephrologist, of a patient with biopsy-proven WHO Class III, IV or V lupus nephritis.	The PBAC deferred its decision on the submission for mycophenolate sodium (MPS) until there is further discussion with the sponsor regarding the approach to the economic modelling as well as further clarification regarding the status of the TGA consideration of MPS for the treatment of lupus nephritis.
		Sponsor's comments:	Novartis looks forward to working with the PBAC to progress this application.
Testosterone, solution in metered-dose pump, 30 mg in 1.5 mL per dose, 60 doses, 110 mL, Axiron® Eli Lilly Australia Pty Ltd Major submission	Testosterone replacement therapy	Authority Required listing for the treatment of: i) androgen deficiency in males with established pituitary or testicular disorders ii) androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than ageing, and meet certain criteria. iii) micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.	The PBAC deferred making a final recommendation pending a decision by the TGA Delegate on the registration of testosterone solution.

		Sponsor's comments:	The sponsor has no comment.
Velaglucerase alfa, powder for IV infusion, 400 units in 4 mL, Vpriv® Shire Australia Pty Limited Major submission	Type 1 Gaucher disease	Request inclusion on the Life Saving Drugs Program (LSDP) for the treatment of type 1 Gaucher disease in a patient who meets certain criteria.	The PBAC deferred its decision on the submission for velaglucerase pending the finalisation of the TGA's evaluation which will determine the place in therapy of velaglucerase.
		Sponsor's comments:	Shire welcomes that the PBAC recognises that if the TGA recommends velaglucerase as an alternative first line ERT, that there is an inherent acceptance that velaglucerase meets the criteria for funding through the LSDP. A minor submission will now be submitted to advance this as requested, however Shire proposes that more detailed processes are developed for deferrals for submissions for LSDP listings.