JULY 2012 PBAC MEETING OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX, lyophilised powder for injection, 100 units, Botox®, Allergan Pty Ltd Major submission	Urinary incontinence	Extend the current Section 100 (Botulinum Toxin Program) listing to include the treatment of urinary incontinence due to neurogenic detrusor overactivity in patients who are not adequately managed by anticholinergic medication.	The PBAC considered that the cost effectiveness was uncertain, and that the utilisation and financial estimates were uncertain. The PBAC deferred the submission to seek further information from MSAC regarding the cost of administration and monitoring and from the sponsor regarding the economic model and utilisation.
		Sponsor's comments:	Allergan is committed to ensuring that patients suffering from urinary incontinence due to neurogenic detrusor overactivity get access to Botox® as soon as possible. Allergan is working with the PBAC and MSAC to ensure that a recommendation can be made at the earliest opportunity.
IVABRADINE, tablet, 5 mg and 7.5 mg (as hydrochloride), Coralan®, Servier Laboratories (Australia) Pty Ltd Major submission	Heart failure	Re-submission for an Authority Required listing for the treatment of symptomatic systolic heart failure in patients in sinus rhythm, with a heart rate of at least 75 beats per minute (bpm), measured after 5 minutes rest, who are stabilised on optimal heart failure therapy, which must include an ACE inhibitor or angiotensin II antagonist and a beta blocker (unless intolerant or contraindicated).	The PBAC deferred the submission to allow verification of the revised ICERs and clarification of the estimates of usage and cost to the PBS resulting from the proposed restriction changes, as well as an assessment of the feasibility of the proposed restriction.
		Sponsor's comments:	The sponsor has no comment.
VEMURAFENIB, tablet, 240 mg, Zelboraf® Roche Products Pty Limited Major submission	Melanoma	Authority Required listing for initial and continuing treatment of previously untreated unresectable stage IIIC or stage IV melanoma in patients positive for the serine/ threonine-protein kinase B-raf (BRAF) V600 mutation, or alternatively BRAF V600 mutation with an ECOG of 0 or 1, who do not have progressive disease.	The PBAC deferred consideration of this application to obtain further information from the sponsor and from the MSAC.

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		Sponsor's comments:	The sponsor has no comment.