JULY 2010 PBAC MEETING OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENT
Eculizumab, solution concentrate for I.V. infusion, 300 mg in 30 mL, Soliris® Alexion Pharmaceuticals Australasia Pty Ltd Minor submission	Monoclonal antibody for use in paroxysmal nocturnal haemoglobinuria	To request the PBAC: - provide advice to the Minister regarding the suitability of eculizumab for inclusion on the Life Saving Drugs Program (LSDP) for treatment of paroxysmal nocturnal haemoglobinuria (PNH) under the revised LSDP funding criteria and conditions; - consider the proposed initiation and continuation criteria for eculizumab for the LSDP which endeavours to identify those patients with PNH who would benefit most from treatment with eculizumab.	The PBAC deferred the submission to allow the sponsor time to obtain further data before making a decision on whether eculizumab qualifies for the revised funding criteria and conditions (effective May 10th 2010) of the Life Saving Drugs Program (LSDP).
		Sponsor's comments:	Alexion received advice and specific questions from the July 2010 PBAC meeting. This has formed the basis for another response by Alexion to the August 2010 Special PBAC meeting. Alexion will continue to work with the PBAC to assist in any way required for the Committee to make its decision on this key revised criterion for the LSDP.