JULY 2005 PBAC OUTCOMES - "1st time" Decisions not to Recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
DOCETAXEL 20 mg and 80 mg Injection, Taxotere® Sanofi Aventis Group Major submission	Anti-cancer drug used to treat prostate cancer, breast cancer, ovarian cancer and lung cancer	Authority Required listing *for the treatment of androgen independent (hormone refractory) prostate cancer.*	The PBAC rejected the submission because of uncertain and unacceptable cost-effectiveness.
		Sponsor's comments	The sponsor disagrees with the decision but needs to clarify the decision with the PBAC.

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ETANERCEPT vial powder for injection, 25 mg, Enbrel® Wyeth Australia Pty Ltd Major submission	Used to treat inflammatory diseases such as chronic plaque psoriasis	Authority required listing *for the treatment of certain patients with severe chronic plaque psoriasis.*	Despite good evidence of clinical effectiveness and a demonstrated clinical need for a drug to treat this group of patients, the PBAC rejected the submission because of uncertain and unacceptable cost-effectiveness.
		Sponsor's comments	The sponsor will be making a re-submission and looks forward to continuing to work with the PBAC. The sponsor refers you to its website for further information. www.wyeth.com.au

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RISPERIDONE injection (long acting), 25 mg, 37.5 mg and 50 mg, Risperdal Consta® Janssen-Cilag Pty Ltd Minor submission	Used to treat schizophrenia	Add to Section 100 *for the treatment of schizophrenia in patients whose illness requires supervision and treatment at hospital outpatient clinics*	The PBAC rejected the submission because of advice that the problem that had been experienced with access by a limited number of patients to risperidone injection has been resolved.
		Sponsor's comments	Janssen-Cilag intends to work collaboratively with the Highly Specialised Drugs Working Party and clinicians to monitor patient access to Risperdal Consta under the current listing.