NOVEMBER 2018 PBAC OUTCOMES – DEFERRALS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BOTULINUM TOXIN TYPE A Lyophilised powder for injection 100 units Botox® Allergan Australia Pty Ltd Change to listing (Major Submission)	Focal spasticity of the lower limb	Resubmission to request an extension to the current Section 100 (Botulinum Toxin Program) listing to include the treatment of lower limb focal spasticity in adults following stroke, who meet certain conditions.	The PBAC deferred making a recommendation on the Section 100 Authority Required listing of botulinum toxin type A (BOTOX®) for the treatment of lower limb focal spasticity following stroke. In deciding to defer, the PBAC noted the clinical need in the proposed population and acknowledged that, for some patients, a clinically meaningful response defined by an improvement in the Modified Ashworth Scale (MAS) of at least one was achieved, and that improvements in MAS were accompanied by other functional improvements. The PBAC noted that the two key trials, REFLEX and Trial 512, consisted of a single injection during a randomised, double blind phase, followed by up to three injections in an open label phase. The PBAC considered that there was a lack of comparative evidence beyond the first injection. The PBAC also noted the limited data for the treatment of spasticity other than that causing plantar flexion of the ankle or equinovarus foot deformity. The PBAC considered that the magnitude of the benefit of BOTOX® was small following the first cycle and, although comparative data were unavailable beyond the first cycle, the PBAC noted that continued responses were observed in those who chose to continue with subsequent treatments. The PBAC considered that BOTOX® was inferior in terms of safety compared to standard of care/placebo. The PBAC noted that the economic model was a cost-utility analysis based on a stepped evaluation of the MAS results from the REFLEX trial. The PBAC considered that the approach was appropriate and that the model time horizon (five years) was consistent with the clinical view. However, the PBAC considered that the incremental cost-effectiveness ratio was high and highly sensitive to the probability of response. The PBAC considered that the uncertainty surrounding the magnitude of the treatment effect of BOTOX® was unlikely to be reduced by future high quality data. The PBAC considered that the uncertainty surrounding the incremental benefit of BOTOX® could be mitigated through the requested price or the implementation of an utilisation cap.
		Sponsor Comment:	The sponsor had no comment.

NOVEMBER 2018 PBAC OUTCOMES – DEFERRALS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4; Injections 50 mg in 1 mL single use pre-filled syringes, 4 Brenzys® Merck Sharp & Dohme (Australia) Pty Limited Change to recommended listing (Minor Submission)	Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis	To request changes to the current Initial 1, Initial 2 and First Continuing restrictions for Brenzys®, including changing the restriction level to allow telephone authority.	The PBAC deferred its consideration of the proposed biosimilar uptake drivers and requested the Department to engage in broader biosimilar policy discussions to determine the feasibility of the request for additional uptake drivers from a policy and implementation perspective regarding these requests.
		Sponsor Comment:	MSD is encouraged by the PBAC's request for the Department to engage in broader biosimilar policy discussions, and will continue to work with both the Department and the PBAC towards implementation of these uptake drivers.

NOVEMBER 2018 PBAC OUTCOMES – DEFERRALS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TOCILIZUMAB Injection 162 mg in 0.9 mL pre-filled pen Injection 162 mg in 0.9 mL pre-filled syringe Actemra® Roche Products Pty Ltd Change to listing (Major Submission)	Giant Cell Arteritis	To request an Authority Required listing for the treatment of giant cell arteritis.	The PBAC deferred making a decision regarding the listing tocilizumab for the treatment of giant cell arteritis (GCA). The PBAC noted that the key trial (the GiACTA trial) found that tocilizumab (weekly or fortnightly) was associated with a statistically significant increase in response rates compared with placebo plus a 52-week prednisone taper, and considered this was an important clinical benefit in this condition. The PBAC considered that tocilizumab treatment for GCA was likely to be cost-effective given: the price reduction offered in the pre-PBAC response; that a proportion of patients could be treated fortnightly (rather than weekly); and that tocilizumab treatment would be limited to 12 months in line with the trial evidence. The PBAC deferred making a decision to seek further information regarding the imaging and biopsy requirements for diagnosis of GCA for the restriction and for the financial caps to be revised to account for fortnightly dosing. In deciding to defer, the PBAC considered there was a high unmet clinical need for effective treatments for GCA particularly given the adverse events associated with corticosteroids in this population who are often older patients with comorbidities, and the limited treatment options available.
		Sponsor Comment:	Roche is committed to addressing the outstanding matters raised by PBAC to bring tocilizumab to patients with GCA at the earliest opportunity.