

July 2006 PBAC Outcomes - Deferrals

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Outcome and Comment
<p>Diphtheria and tetanus vaccine for adult use, injection 0.5 mL in pre-filled syringe, adsorbed. Diluted for adult use, ADT[®] CSL Limited Minor submission</p>	<p>Vaccine</p>	<p>Listing of replacement ADT vaccine for Doctor's Bag (not as yet TGA registered) which is sourced from a third party. A higher price than for current listing is requested.</p>	<p>The PBAC deferred the submission to seek the views of the sponsor and the Australian Technical Advisory Group on Immunisation on the suitability of the adult/adolescent formulation of diphtheria – tetanus-acellular pertussis vaccine for this purpose.</p>
		<p><i>Sponsor's comment</i></p>	<p>The sponsor needs to clarify the decision with the PBAC.</p>
<p>Dornase alfa, solution for inhalation, 2.5 mg (2,500 units) in 2.5 mL ampoule, Pulmozyme[®], Roche Products Pty Ltd Minor submission</p>	<p>Treatment for cystic fibrosis</p>	<p>A change to the restriction to allow children less than 5 years of age to receive treatment.</p>	<p>In view of expert advice received that it is not possible to objectively measure improvements with treatment of patients less than 5 years of age, the PBAC again deferred the submission to seek advice on a possible restriction to target the most severe patients in whom dornase alfa is more likely to be cost-effective. The PBAC expressed sympathy with the request and decided to seek a meeting with the expert clinicians to try and reach an agreed position.</p>
		<p><i>Sponsor's comment</i></p>	<p>The sponsor agrees with the PBAC decision.</p>

<p>Goserelin acetate and bicalutamide, subcutaneous implant 3.6 mg- tablet 50 mg x 28; subcutaneous implant 10.8 mg-tablet 50 mg x 28, and subcutaneous implant 10.8 mg-tablet 50 mg x 84 (Zoladex Plus®) AstraZeneca Pty Ltd</p> <p>Minor submission</p>	<p>Prostate cancer</p>	<p>Authority required listing for metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required.</p>	<p>The PBAC deferred the submission to seek the sponsor's comments on concerns about the proposed listing.</p>
		<p><i>Sponsor's comment</i></p>	<p>AstraZeneca will be responding to the PBAC's request</p>