PUBLIC SUMMARY DOCUMENT

Product: Travoprost with timolol maleate, eye drops, 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL, DuoTrav®

Sponsor: Alcon Laboratories (Australia) Pty Ltd

Date of PBAC Consideration: March 2007

1. Purpose of Application

The submission sought a change to the restricted benefit listing of DuoTrav to include patients not adequately controlled on other beta-blockers or other prostaglandin analogues.

2. Background

DuoTrav was recommended for listing at the PBAC's July 2006 meeting on a cost minimisation basis with Xalacom® (latanoprost 0.005% with timolol 0.5%).

3. Registration Status

As at 8 September 2006 travoprost with timolol maleate (DuoTrav®) was recorded in the Australian Register of Therapeutic Goods (ARTG) as being indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension for whom single agent therapy provides insufficient intraocular pressure reduction.

4. Listing Requested and PBAC's View

Restricted benefit
Reduction of elevated intra-ocular pressure in patients with open angle glaucoma, who are not adequately controlled with beta-blockers or prostaglandin analogues.
Reduction of elevated intra-ocular pressure in patients with ocular hypertension, who are not adequately controlled with beta-blockers or prostaglandin analogues.

See Recommendation and Reasons for the PBAC's view

5. Clinical Place for the Proposed Therapy

This fixed combination product will provide a therapeutic alternative where a single drug treatment for glaucoma or ocular hypertension is not effective.

6. Comparator

The submission nominated concomitant administration of latanoprost and timolol as the comparator.

7. Clinical Trials

A double masked, randomised parallel group, multicentre, active control trial comparing the efficacy and safety of DuoTrav® to concomitant latanoprost plus timolol in 156 patients previously treated with latanoprost plus timolol was presented in the submission.

This trial had not been published at the time of the submission.

8. Results of Trials

The results of the key trial are summarised in the following tables.

Mean IOP (mmHg), Change from Baseline (mmHg), and percent IOP Change from Baseline (ITT Data)

	Week 2	Week 6	Month 3			
Treatment	**8AM**	**8AM**	**8AM**	**10AM**	**4PM**	**8PM**
Travoprost 0.004%/Timolol 0.5%						
Mean IOP	15.3	15.4	15.5	15.1	15.1	14.7
Mean IOP Change	-0.1	-0.0	0.1	0.5	0.5	0.4
Mean % IOP Change	0.0	0.3	1.2	4.6	4.5	3.4
N	73	73	73	71	71	71
Xalatan 0.005%+Timolol 0.5%						
Mean IOP	15.4	15.6	15.5	14.8	14.9	14.8
Mean IOP Change	-0.0	0.2	0.0	0.1	0.3	0.2
Mean % IOP Change	-0.2	1.3	0.3	0.9	2.6	2.0
N	75	75	75	73	73	73

Estimates based on descriptive statistics.

Mean IOP Change from Baseline (mmHg) Comparison (ITT Data)

	Baseline (mean IOP)				Week 2	Week 6	Month 3			
Treatment	**8AM**	**10AM**	**4PM**	**8PM**	**8AM**	**8AM**	**8AM**	**10AM**	**4PM**	**8PM**
Travoprost 0.004%/ Timolol 0.5%	15.4	14.6	14.5	14.4	-0.1	-0.0	0.1	0.5	0.5	0.4
Xalatan 0.005%+ Timolol 0.5%	15.4	14.7	14.6	14.7	-0.0	0.2	0.0	0.1	0.3	0.2
Difference	-0.0	-0.1	-0.1	-0.3	-0.1	-0.2	0.1	0.4	0.2	0.2
P-value*	-	-	-	-	0.8727	0.5025	0.8260	0.3883	0.5301	0.5735

*P-value from two sample t-test

9. Clinical Claim

The submission described DuoTrav® as being no worse than latanoprost plus timolol in terms of effectiveness and toxicity.

10. Economic Analysis

Neither a preliminary economic evaluation nor a modelled economic evaluation was presented.

11. Estimated PBS Usage and Financial Implications

The submission estimated that the likely number of packs dispensed per year would be 10,000 – 50,000 by Year 3 of listing, while the financial cost to the PBS minus any savings in use of other drugs was estimated to be < $10 million per year.

12. Recommendation and Reasons

Based on the data presented in the submission, the PBAC recommended expanding the current listing, on a cost minimisation basis as previously, to include patients not adequately controlled on latanoprost. The PBAC noted that the sponsor agreed to the wording of the restriction as proposed by the Secretariat.

Recommendation

TRAVOPROST with TIMOLOL MALEATE, eye drops, 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5mL

Amend the restriction to read:

> Restricted benefit
> Reduction of elevated intra-ocular pressure in patients with open angle glaucoma, who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops;
> Reduction of elevated intra-ocular pressure in patients with ocular hypertension, who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops.

Maximum Quantity: ‡1
Repeats: 5

13. Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

14. Sponsor's Comment

Alcon accepts the Decision