

**6.08 POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL,  
Eye drops 4mg-3mg per mL, single dose units 0.8 mL,  
30,  
Systane<sup>®</sup>,  
Alcon Laboratories (Australia) Pty Ltd**

**1 Purpose of Submission**

1.1 The Category 4 submission sought to list a new form of polyethylene glycol 400 with propylene glycol (Systane) with a pack of 30 x 0.8 mL unit doses to replace the PBS-listed Systane with a pack of 28 x 0.8 mL unit doses.

**2 Background**

2.1 Although the submission stated that the new listing will replace the existing 28-unit dose pack, no delisting request has been received to date. The sponsor indicated in their pre-PBAC response that they intended to seek deletion of the 28-unit pack from the PBS in August 2022.

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

**3 Requested Listing**

3.1 The submission requested the following changes:

Add new medicinal product as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL					
<i>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Systane</i>
Restriction Summary 6172 / ToC: 6172: Authority Required: Streamlined <i>NO CHANGES</i>					
<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Optometrists					
<b>Restriction type:</b> <input type="checkbox"/> Authority Required – Streamlined					
[7869]	Indication: Severe dry eye syndrome				
[7875]	Clinical criteria:				
[7874]	Patient must be sensitive to preservatives in multi-dose eye drops				

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polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses		NEW	2	2	5	Systane
Restriction Summary 6172 / ToC: 6172: Authority Required: Streamlined <i>NO CHANGES</i>						
<b>Category / Program:</b> GENERAL – General Schedule (Code GE)						
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners						
<b>Restriction type:</b> <input type="checkbox"/> Authority Required – Streamlined						
[7869]	Indication: Severe dry eye syndrome					
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*For more detail on PBAC’s view, see section 6 PBAC outcome.*

## **4 Comparator**

- 4.1 The submission nominated polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses as the comparator. The PBAC advised this was appropriate.

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

## **5 Consideration of the evidence**

### ***Sponsor Hearing***

- 5.1 There was no hearing for this item.

### ***Consumer comments***

- 5.2 The PBAC noted that no consumer comments were received for this item.

### ***Clinical claim***

- 5.3 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses compared with polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses.

### ***Pricing consideration***

- 5.4 The sponsor proposed an approved ex-manufacturer price (AEMP) of \$9.74 for Systane eye drops (30 x 0.8 mL unit doses), reflecting an adjustment proportionate to the change in pack size from the current Systane eye drops (28 x 0.8 mL unit doses) which has an AEMP of \$9.09. The PBAC noted that the proposed price per unit dose is

\$0.32, which is equal to the current price per unit of Systane 28 x 0.8 mL unit dose pack.

**Table 1: Essential element for Systane (polyethylene glycol 400 with propylene glycol) eye drops.**

	Form	Pricing Quantity	Max. Qty (units)	AEMP (\$)	DPMQ (\$)
<b>Proposed</b>	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30	1	2	\$9.74	\$33.02
<b>Current</b>	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28	1	2	\$9.09	\$31.62

Source: Table 1, p1 of cover letter and PBS Ex-manufacturer prices (excluding Efficient Funding of Chemotherapy) - 1 September 2021.

### **Estimated PBS utilisation and financial implications**

- 5.5 The submission stated that the change in pack size is expected to result in a small cost saving to the PBS due to wholesaler and pharmacy mark-ups and fees, but noted this cost saving will be partially offset by the reduction in patient co-payments. This partial offset is expected to result in a minor net save to the PBS/RPBS.
- 5.6 Table 2 presents the sponsor's estimated extent of use, cost of the new pack size of Systane to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.
- 5.7 The submission claimed that the cost of polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses (Systane) to the PBS/RPBS is expected to be \$10 million to < \$20 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).
- 5.8 The submission claimed that this listing is expected to have an impact of net cost saving on the utilisation of existing PBS/RPBS listings of Systane over six years (Year 1 net cost saving to Year 6 net cost saving).
- 5.9 The submission stated that the estimated net save to the PBS/RPBS for the new listings of Systane 30 unit dose pack of \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million) did not include a calculation of a reduced number of patient co-payments which would reduce the net saving.

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Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use</b>						
Number of PBS scripts	1	1	2	3	3	3
Number of RPBS scripts	4	4	4	4	4	5
Total number of scripts	1	2	2	3	3	3
<b>Drug costs to PBS</b>						
Cost of Systane to PBS	6	6	6	6	6	6
Less co-payments	6	6	6	6	6	6
Net cost to PBS	6	6	6	6	6	6
<b>Drug costs to RPBS</b>						
Cost of Systane to RPBS	6	6	6	6	6	6
Less co-payments	6	6	6	6	6	6
Net cost to RPBS	6	6	6	6	6	6
<b>Cost of affected PBS listing</b>						
Cost of affected PBS listings of Systane	6	6	6	6	6	6
Less PBS co-payments	6	6	6	6	6	6
Net Cost of affected PBS listings of Systane	6	6	6	6	6	6
<b>Cost of affected RPBS listings</b>						
Cost of affected RPBS listings of Systane	6	6	6	6	6	6
Less RPBS co-payments	6	6	6	6	6	6
Net Cost of affected RPBS listings of Systane	6	6	6	6	6	6
<b>Estimated net financial implications</b>						
Net cost to PBS	6	6	6	6	6	6
Net cost to RPBS	6	6	6	6	6	6

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Utilisation and cost model workbook from the submission. Note that the workbook has not been externally evaluated.

The redacted values correspond to the following ranges:

<sup>1</sup> 80,000 to < 90,000

<sup>2</sup> 90,000 to < 100,000

<sup>3</sup> 100,000 to < 200,000

<sup>4</sup> 500 to < 5,000

<sup>5</sup> 5,000 to < 10,000

<sup>6</sup> \$0 to < \$10 million

5.10 As a Category 4 submission, the financial estimates analysis has not been independently evaluated.

For more detail on PBAC's view, see section 6 PBAC outcome.

## 6 PBAC Outcome

6.1 The PBAC recommended listing a new form of polyethylene glycol 400 with propylene glycol (Systane) with a pack size of 30 x 0.8 mL unit doses, at the same price per unit as the currently listed pack size.

6.2 The PBAC noted that the submission estimated a small net save to the PBS/RPBS. The PBAC considered the estimated save to be uncertain and likely minor.

- 6.3 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because the new form of polyethylene glycol 400 with propylene glycol is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over the currently listed form, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

## Outcome

Recommended

## 7 Recommended listing

7.1 Add new item:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
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Patient must be sensitive to preservatives in multi-dose eye drops					
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<b>Restriction type:</b> <input type="checkbox"/> Authority Required – Streamlined					
Indication: Severe dry eye syndrome					
Clinical criteria:					
Patient must be sensitive to preservatives in multi-dose eye drops					

***This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.***

## **8 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **9 Sponsor's Comment**

The sponsor had no comment.