

## **7.12 PROPRANOLOL**

**oral liquid 3.75 mg per mL, 120 mL**

**Hemangiol<sup>®</sup>, Pierre Fabre Australia Pty Ltd**

### **1 Purpose of Application**

- 1.1 The minor resubmission sought an Authority Required listing for the treatment of proliferating infantile hemangioma requiring systemic therapy at an adjusted price in response to PBAC advice from the November 2015 meeting and negotiations with the Department.

### **2 Requested listing**

- 2.1 The minor resubmission did not propose any additional changes to the recommended listing in the March 2015 minor submission.

### **3 Background**

- 3.1 Hemangiol<sup>®</sup>(propranolol oral liquid) is TGA registered for the following indications:  
Treatment of proliferating infantile hemangioma requiring systemic therapy:  
Life-threatening hemangioma.  
Ulcerated hemangioma with pain and/or lack of response to simple wound care measures.  
Hemangiomas with a risk of permanent scars or disfigurement.
- 3.2 At its March 2015 meeting, the PBAC recommended the listing of propranolol oral liquid as an Authority Required (telephone) listing on the general schedule for the treatment of proliferating infantile haemangioma requiring systemic therapy.
- 3.3 The PBAC was satisfied that Hemangiol<sup>®</sup> provides the same benefits as seen with either of the currently available alternatives, namely, Auspman propranolol solution or compounded propranolol liquid, and that these are the therapies most likely to be replaced. Auspman propranolol solution or compounded propranolol liquid are therefore the most appropriate comparators.

- 3.4 The PBAC noted that the cost consequence method used to derive the proposed price was unsubstantiated and resulted in an unacceptably high price, noting that the proposed price of Hemangiol<sup>®</sup> was [REDACTED] of propranolol tablets. The PBAC considered that Hemangiol<sup>®</sup> should be cost minimised against the currently available Auspman propranolol solution with a modest price premium to be negotiated between the Sponsor and the Department in acknowledgement that Hemangiol<sup>®</sup> is a commercially available is likely to have access benefits for patients.
- 3.5 At its November 2015 meeting, the PBAC considered a resubmission which sought a higher price for Hemangiol<sup>®</sup> compared to what was recommended at the March 2015 PBAC meeting. The resubmission proposed that 100% of the price for Hemangiol<sup>®</sup> be based on the price of compounded propranolol solution. This proposal was based on advice from hospital pharmacists that the majority of the dispensing of propranolol liquid would be from the community pharmacy setting, and that in this setting most patients would be supplied compounded propranolol liquid rather than the Auspman propranolol solution.
- 3.6 The November 2015 resubmission proposed to establish a reference price for compounded propranolol liquid by conducting a survey of 131 community pharmacies for a 900 mg preparation – equivalent to the amount of propranolol contained in the maximum quantity of Hemangiol<sup>®</sup> (2 bottles of 120 mL, 3.75 mg/mL).
- 3.7 The resubmission's requested price of \$ [REDACTED] (DPMQ) was based on the average price for a 900 mg preparation of compounded propranolol liquid (\$ [REDACTED]) plus a premium factor of two. The requested price was a [REDACTED]% reduction from the price proposed in the March 2015 submission.
- 3.8 The PBAC rejected the proposed price for Hemangiol<sup>®</sup>. The PBAC noted the resubmission's proposed methodology to establish a reference price for compounded propranolol liquid, however it considered that the proposed price for Hemangiol<sup>®</sup>, which includes a premium factor of two over the reference price of compounded propranolol liquid, to be unsubstantiated.
- 3.9 The PBAC considered that the price of Hemangiol<sup>®</sup> needs to reflect the price of the ready-prepared Auspman oral solution as this is the current standard of care for this treatment setting.

*For more detail on PBAC's view, see section 7 "PBAC outcome."*

## 4 Comparator

- 4.1 The minor resubmission proposed a weighted combination of 99.5% compounded propranolol (\$██████ per 900 mg) and 0.5% Auspman propranolol solution (\$██████ per 900 mg) as the price comparator. This was based on the resubmission's assumption of the likely dispensing setting of Hemangirol®, considering the price of Auspman propranolol solution and the average price of compounded propranolol dispensed in retail pharmacies.

*For more detail on PBAC's view, see section 7 "PBAC outcome."*

## 5 Consideration of the evidence

### ***Sponsor hearing***

- 5.1 There was no hearing for this item as it was a minor submission.

### ***Consumer comments***

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

### ***Clinical need***

- 5.3 The current minor resubmission reiterated the clinical need for a TGA approved propranolol oral liquid. The minor resubmission claimed that the Auspman propranolol liquid was only legally available in WA and emphasised that the limited number of compounding pharmacies in Australia make access for some patients difficult.

### ***Economic analysis***

- 5.4 The minor resubmission presented a cost consequence analysis which compared the cost of treatment with Hemangirol® to the current options for accessing propranolol oral liquid (Auspman propranolol solution and compounded propranolol). The requested price for Hemangirol® is shown in Table 1 below.

Table 1: Requested price for propranolol oral liquid

Max quantity (bottles per script)	Ex-manufacturer price	Wholesaler mark-up	Ex-manufacturer price + wholesaler mark-up	Pharmacy mark-up	Ex-manufacturer price + wholesaler mark-up + pharmacy markup Dispensing fee	Dispensing fee	DPMQ
2	\$ [REDACTED]	7.52%	\$ [REDACTED]	\$9.88	\$ [REDACTED]	\$7.02	\$ [REDACTED]

Source: Page 41 of the minor resubmission

- 5.5 The minor resubmission stated that the proposed DPMQ is a [REDACTED] % decrease from the DPMQ proposed in the March 2015 major submission (\$ [REDACTED]).
- 5.6 The proposed Ex-manufacturer price for Hemangiol® is based on the weighted combination price of Auspman propranolol solution and compounded propranolol (\$ [REDACTED]) plus the cost per script of the services provided with Hemangiol® (\$ [REDACTED]) and an additional premium of \$ [REDACTED] over compounded propranolol.
- 5.7 The minor resubmission claimed that the cost of \$ [REDACTED] per script of Hemangiol® represents the additional costs associated with pharmacovigilance and risk minimisation measures surrounding Hemangiol® dispensing.
- 5.8 It is noted that the minor resubmission’s method to determine a price for Hemangiol® differs from that which the Department proposed in the November 2015 Minutes. The weighting method proposed by the Department assumed dispensing of propranolol liquid to be 91% using compounded propranolol liquid and 9% Auspman propranolol solution. The DPMQ calculated using this alternative weighting method is \$ [REDACTED].
- 5.9 The weightings were based on the sponsor’s November 2015 resubmission that the continued dispensing of propranolol liquid was likely to be from a community pharmacy (91%) using compounded propranolol liquid, with the initial script dispensed from the hospital pharmacy with the Auspman solution (9%).
- 5.10 The Department has previously advised the sponsor that based on the March 2015 and November 2015 PBAC advice, it would not be in a position to recommend listing at a DPMQ higher than \$ [REDACTED] for Hemangiol®.

**Drug cost/patient/course: \$ [REDACTED].**

5.11 The minor resubmission estimated the total cost per course of treatment with Hemangioli® to be \$ [REDACTED] based on an estimated 8.5 bottles for 6 months of treatment, with 11.5% of patients requiring an additional 6 months of treatment for recurrence of the disease.

**Estimated PBS usage & financial implications**

5.12 The minor submission estimated a net cost to the PBS of \$ [REDACTED] in Year 1 of listing, with a total net cost to the PBS of \$ [REDACTED] over the first 5 years of listing. This is summarised in Table 2 below as well as the expected patient/prescription numbers.

**Table 2: Estimated use and financial implications**

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of patients treated	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Number of prescriptions	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Average patient co-payment	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net cost to the PBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

Source: Tables 14, 15 and 16 of the minor submission

For more detail on PBAC’s view, see section 7 “PBAC outcome.”

**6 PBAC Outcome**

6.1 The PBAC rejected the request for a higher price and reaffirmed its recommendation from the March 2015 meeting.

6.2 The PBAC considered that the resubmission’s cost consequence method used to derive the proposed price was unsubstantiated and resulted in a price that was unacceptably high. The PBAC considered that while the resubmission’s proposed DPMQ is [REDACTED]% lower than the DPMQ proposed in the November 2015 submission, the magnitude of the price advantage of resubmission’s proposed DPMQ over the price of compounded propranolol liquid remained significant and was not adequately justified in the resubmission.

6.3 The PBAC noted that the proposed price included a significant cost of \$ [REDACTED] per script that the resubmission attributed to quality assurance, pharmacovigilance and

risk minimisation measures. The PBAC considered this to be inappropriate.

- 6.4 The PBAC noted that although Hemangirol® is a commercially available product, which would likely to have some benefits for patients in terms of access, the patient population have adequate access to alternative therapies. The PBAC therefore considered that the benefits gained in terms of access for patients from the listing of Hemangirol® did not justify the proposed price advantage of Hemangirol® over alternative therapies.
- 6.5 In the absence of any clinical data to support the requested price of Hemangirol®, the PBAC considered that the Department’s proposed price represented a fair price for Hemangirol®, and advised that a higher price would not be cost-effective.
- 6.6 The PBAC noted that this submission was not eligible for an Independent Review as it was a pricing request.

**Outcome:**

Rejected

## **7 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.

## **8 Sponsor’s Comment**

The sponsor will continue to work with the Department to explore all feasible options with the PBAC and Department to make Hemangirol available to all Australian patients.