

**5.15 MESALAZINE,  
Tablet 1600 mg (enteric coated),  
Asacol<sup>®</sup>,  
Chiesi Australia Pty Ltd**

**1 Purpose of Application**

- 1.1 The minor submission requested a General Schedule, Restricted Benefit listing of a new strength of mesalazine (Asacol<sup>®</sup>) 1600 mg enteric coated tablets (herein referred to as Asacol 1600) for the treatment of ulcerative colitis under the same conditions as the currently PBS listed mesalazine 800 mg enteric coated tablets (herein referred to as Asacol 800).

**2 Background**

***Registration status***

- 2.1 Asacol 1600 was TGA approved on 6 June 2020 for the treatment of mild to moderate ulcerative colitis and maintenance of remission in adults.

***Previous PBAC consideration***

- 2.2 Asacol 1600 has not previously been considered by the PBAC.

**3 Requested listing**

- 3.1 The minor submission requested Asacol 1600 be made available through the PBS under the same circumstances as the currently PBS listed Asacol 800. Suggestions and additions proposed by the Secretariat are added in italics and suggested deletions are crossed out with strikethrough.

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
MESALAZINE					
mesalazine 1600 mg enteric tablet, 60	NEW	2	120	5 4	Asacol
mesalazine 800 mg enteric tablet, 90	11210B	2-1	480-90	5	Asacol
<b>Restriction Summary 9445 / Treatment of Concept: 9444</b>					
	<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 - CTO				
	<b>Restriction Type:</b> <input checked="" type="checkbox"/> Restricted benefit				
	<b>Administrative Advice:</b> Not for the treatment of Crohn disease				
	<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.				
	<b>Indication:</b> Ulcerative colitis				

- 3.2 No changes were requested to the current restriction for Asacol 800, which at the time of consideration, was a Restricted benefit for the treatment of ulcerative colitis.
- 3.3 The sponsor agreed that the maximum number of repeats should be four to allow for a maximum of six months' supply for chronic therapy based on a maximum dose of 4.8 g per day (pre-PBAC response).
- 3.4 The sponsor also agreed to the proposal to reduce the maximum quantity of Asacol 800 to 90 should Asacol 1600 be listed (pre-PBAC response).

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

## 4 Comparator

- 4.1 The minor submission nominated Asacol 800 (two tablets per day) as the main comparator of Asacol 1600 (one tablet per day) because Asacol 800 is the treatment most likely to be replaced by prescribers in practice.
- 4.2 The submission noted Asacol 400, which is not PBS listed, was used as the comparator in clinical trial evidence.

*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 as it was a minor submission.

### **Consumer comments**

- 5.2 The PBAC noted and welcomed the input from organisations (1) via the Consumer Comments facility on the PBS website. Crohn's & Colitis Australia (CCA) supported the

addition of Asacol 1600 to provide greater choice for consumers.

### **Clinical trials**

- 5.3 The minor submission presented two clinical trials:
- TP0503-I (N=871), a Phase 3, randomised, active-controlled, double-blind, multi-centre, non-inferiority trial was used to evaluate the safety and efficacy of Asacol 1600 compared to Asacol 400;
  - TP0503-II (N=727), an open label extension trial, where 727 of the 871 patients from TP0503-I entered, was used to assess the long-term safety and tolerability of Asacol 1600 administered over a 26-week period.

### **Clinical claims**

- 5.4 The submission claimed one tablet of Asacol 1600 is non-inferior to two tablets of Asacol 800 or four tablets of Asacol 400. The submission also claimed the TGA accepted that two tablets of Asacol 400 was equivalent to one tablet of Asacol 800 and that one tablet of Asacol 1600 was equivalent to four tablets of Asacol 400.
- 5.5 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.

### **Economic analysis**

- 5.6 The proposed approved ex-manufacturer price (AEMP) was \$ [REDACTED], based on the price per mg of the currently PBS listed Asacol 800 (AEMP \$ [REDACTED]).
- 5.7 As a minor submission, the economic analysis has not been independently evaluated.

### **Drug cost/patient/year: \$ [REDACTED]**

- 5.8 The estimated cost/patient/year would be \$ [REDACTED], based on 12 prescriptions per year for the maximum quantity requested at a DPMQ of \$ [REDACTED]. The actual cost will vary due to variations in individual patient needs.

### **Estimated PBS usage & financial implications**

- 5.9 The submission used a market share approach for the utilisation and cost model of Asacol 1600. The submission claimed the mesalazine market is largely mature and well established. The submission reported an annual growth rate of 1.76% calculated from PBS mesalazine tablet utilisation over the previous five years. The submission expected no change to the treated prevalent population.
- 5.10 The submission estimated a net cost to the PBS of \$0 to <\$10 million in Year 6 of listing, with a total net cost to the PBS of \$0 to <\$10 million over the first 6 years of listing. This is summarised in the below table

Table 1: 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 scripts dispensed	█ <sup>1</sup>	█ <sup>2</sup>	█ <sup>3</sup>	█ <sup>3</sup>	█ <sup>3</sup>	█ <sup>3</sup>
<b>Estimated financial implications of Asacol 1600</b>						
Cost to PBS/RPBS	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>
Co-payments	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>
Cost to PBS/RPBS less co-payments	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>
<b>Estimated financial implications of Asacol 800</b>						
Cost to PBS/RPBS	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>
Co-payments	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>
Cost to PBS/RPBS less co-payments	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>
<b>Net financial implications of Asacol 1600</b>						
Net cost PBS / RPBS	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>	\$█ <sup>4</sup>

Source: Table 23 and 24 of the submission

The redacted values correspond to the following ranges:

<sup>1</sup>1500 to <5,000

<sup>2</sup>5,000 to <10,000

<sup>3</sup>10,000 to <20,000

<sup>4</sup>\$0 to <\$10 million

5.11 As a minor submission, the financial estimates have not been independently evaluated.

### Quality use of medicines

5.12 The submission claimed Asacol 1600 would reduce pill burden and frequency of multi-day dosing, which lowers the risk of non-adherence in ulcerative colitis patients.

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

## 6 PBAC Outcome

6.1 The PBAC recommended the General Schedule, Restricted Benefit listing of mesalazine, 1600 mg enteric coated tablets for the treatment of ulcerative colitis under the same circumstances as the currently PBS listed Asacol 800.

6.2 The PBAC recommended the listing of Asacol 1600 on a cost-minimisation basis, based on the price per mg of the currently PBS listed Asacol 800. The equi-effective doses are: one Asacol 1600 tablet and two Asacol 800 tablets. Consistent with its advice in March 2017 for the Asacol 800, the PBAC considered that the Asacol 1600 could be cost-minimised to any oral formulation of mesalazine on the PBS.

6.3 The PBAC advised that the maximum number of repeats should be four, to provide six months' supply at the maximum recommended dose.

- 6.4 The PBAC advised that the maximum quantity for Asacol 800 should be reduced to 90, as it will primarily be prescribed for maintenance treatment where lower doses are required.
- 6.5 The PBAC noted Asacol 1600 would reduce pill burden and frequency of multi-day dosing, which lowers the risk of non-adherence in ulcerative colitis patients.
- 6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Asacol 1600 is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Asacol 800, 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.
- 6.7 The PBAC noted that this submission is not eligible for Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## 7 Recommended listing

- 7.1 Add new 1600 mg strength with the same restriction as Item 11210B.
- 7.2 As a flow-on change of listing the new strength, reduce the maximum quantity of existing 800 mg strength.

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mesalazine 800 mg enteric tablet, 90	11210B	<del>2</del> -1	<del>120</del> -90	5	Asacol
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<b>Indication:</b> Ulcerative colitis					

***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**

Chiesi Australia welcomes the PBAC's decision to recommend Asacol 1600 for the treatment of mild to moderate ulcerative colitis and maintenance of remission in adults.