6.11 MESALAZINE, Suppository 1 g, Sachet containing granules, 1 g per sachet, Pentasa®, Ferring Pharmaceuticals Pty Ltd

1 Purpose of Application

1.1 The minor submission requested a change to the maximum quantity for 1 g suppository and 1 g sachet containing granule forms of the Pentasa® brand of mesalazine, in line with changes to the pack sizes (from 30 to 28 units – suppository and 120 to 100 sachets - granules).

2 Background

2.1 Mesalazine suppositories are currently listed on the PBS as a Restricted Benefit listing for the management of an acute episode of mild to moderate ulcerative proctitis.

2.2 Mesalazine granules are currently listed on the PBS as a Restricted Benefit for ulcerative colitis and Crohn disease.

Registration status

2.3 Mesalazine 1 g suppository was approved by the TGA on 14 November 2003, and mesalazine 1 g modified release granules were approved by the TGA on 21 November 2006.

2.4 In December 2019, the TGA updated the product information for both mesalazine forms to reflect the changes in pack size.

Previous PBAC consideration

2.5 Mesalazine suppositories were initially recommended by the PBAC in December 2003, with a maximum quantity of 28 suppositories. In July 2011, PBAC recommended an increase in the maximum quantity from 28 to 30 suppositories.

2.6 Mesalazine modified release granules were initially recommended by the PBAC in November 2006 with a maximum quantity of 100 sachets. In July 2010, PBAC recommended an increase in the maximum quantity from 100 to 120 sachets.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Requested listing

3.1 The submission requested the following changes to the existing listings:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Name and Manufacturer	
MESALAZINE ~~mesalazine 1 g suppository, 30~~ mesalazine 1 g suppository, 28	8752P	1	~~30~~28	1	Pentasa®	Ferring Pharmaceuticals Pty Ltd
MESALAZINE ~~mesalazine 1 g modified release granules, 120 sachets~~ mesalazine 1 g modified release granules, 100 sachets	2234N	1	~~120~~100	5	Pentasa®	Ferring Pharmaceuticals Pty Ltd

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

4.2 The PBAC noted and welcomed the input from individuals (1), and organisations (1) via the Consumer Comments facility on the PBS website. The comments related to the value of mesalazine for people with ulcerative proctitis and maintaining an affordable price for people requiring mesalazine.

4.3 The PBAC noted the input received from Crohn's and Colitis Australia stated that it was unclear whether the reduced pack size would be accompanied by a reduced pack cost, and that having no equivalent reduction in consumer cost could have a considerable impact for those on limited incomes.

Pricing Matters

4.4 The submission requested that the AEMP for the 1 g suppository and 1 g modified release granules be proportionately adjusted to the change in pack size. Table 1 below shows the requested AEMP and DPMQ for both forms.

Table 1: Requested price for mesalazine 1 g suppository and 1 g modified release granules

Name, restriction, manner of administration, form	Current AEMP per unit	Current AEMP per pack	Requested AEMP per unit	Requested AEMP per pack	Requested DPMQ per pack	Proprietary name and manufacturer
Mesalazine 1 g suppository 28	$2.98	$89.26	$2.98	$83.31	$101.05	Pentasa®, Ferring Pharmaceuticals Pty Limited
Mesalazine 1 g modified release granules, sachets 100	$1.12	$134.17	$1.12	$111.81	$131.70	Pentasa®, Ferring Pharmaceuticals Pty Limited

Source: Table 2: Essential elements for mesalazine (Pentasa®) 1 g suppository and 1g modified release granules, minor submission, pg 2 and current AEMP from pbs.gov.au.

Estimated PBS usage & financial implications

4.5 The submission claimed that the changes to the maximum quantities would result in a net save to the PBS, with the additional wholesaler and pharmacy mark ups and fees, being offset by an increase in patient co-payments. The minor submission estimated the changes to the maximum quantities would result in a cost saving to the PBS of less than $10 million per year. However, the sponsor subsequently provided detailed financial implications, which estimated a net save to the PBS of less than $10 million in Year 6 of listing, with a total net save to the PBS of less than $10 million over the first six years of listing.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Estimated financial implications of mesalazine suppository and granules new pack size						
Cost to PBS/RPBS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Copayments	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cost to PBS/RPBS less copayments	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Estimated financial implications for mesalazine suppository and granules currently listed pack size						
Cost to PBS/RPBS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Copayments	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cost to PBS/RPBS less copayments	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Net financial implications						
Net cost to PBS/RPBS	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]

Source: Collated during evaluation from predicted use and financial implication spreadsheet for granules and suppositories

The redacted table shows that at Year 6, the estimated number of scripts dispensed is less than 10,000.

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

5.1 The PBAC recommended the change in maximum quantity for mesalazine suppositories for the management of an acute episode of mild to moderate ulcerative proctitis and modified release granules for ulcerative colitis and Crohn disease based on the change to pack sizes.

5.2 The PBAC noted that the requested AEMP for both the suppositories and the modified release granules were adjusted proportionately to the change in pack size.

5.3 The PBAC considered that the requested change would not result in any substantive changes in costs to the PBS. The PBAC did not consider that a saving would be realised

to the PBS from the reduced AEMP per pack, as the reduced number of units per pack will result in a proportional increase in packs dispensed per year.

5.4 The PBAC recommended that the Early Supply Rule should continue to apply to mesalazine 1 g modified release, and to continue not to apply to mesalazine 1 g suppository.

5.5 The PBAC recommended that Nurse Practitioner Prescribing arrangements should continue to apply to mesalazine 1 g modified release and 1 g suppository.

5.6 The PBAC noted that this submission is not eligible for Pricing Pathway A under *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2009* because the change to the maximum quantity of mesalazine is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapy and is not expected to address a high and urgent unmet clinical need.

5.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

6 Recommended listing

6.1 Amend pack size descriptions/maximum quantities to read as follows:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Name and Manufacturer	
MESALAZINE mesalazine 1 g suppository, 28	8752P	1	28	1	Pentasa®	Ferring Pharmaceuticals Pty Ltd

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Name and Manufacturer	
MESALAZINE mesalazine 1 g modified release granules, 100 sachets	2234N	1	100	5	Pentasa®	Ferring Pharmaceuticals Pty Ltd

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

7 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.

8 Sponsor's Comment

The sponsor had no comment.