

5.20 DAPSONE, Tablet 50 mg, Dapsomed[®], Medsurge Healthcare Pty Ltd

1 Purpose of Submission

- 1.1 The Committee Secretariat submission sought a General Schedule Unrestricted Benefit listing of a new 50 mg strength of dapsone (Dapsomed[®]; hereafter referred to as DAPSOMED) under the same conditions as the currently listed strengths of dapsone.

2 Background

- 2.1 Dapsone is currently listed on the PBS as an Unrestricted Benefit listing with two strengths: 25 mg tablet (Link Medical Products Dapsone; hereafter referred to as DAPSONE) and 100 mg tablet (DAPSOMED and DAPSONE).

Registration status

- 2.2 DAPSOMED 50 mg tablet (and 100 mg tablet) was TGA registered on 2 December 2024 for dermatitis herpetiformis, leprosy, and actinomycotic mycetoma.
- 2.3 The sponsor provided the TGA approval letter with their submission, which states that DAPSOMED can be considered bioequivalent to DAPSONE.

3 Requested listing

- 3.1 The submission requested the following new listing:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DAPSONE					
dapsone 50 mg tablet, 100	NEW	1	100	1	Dapsomed [®]
Benefit type [new]: Unrestricted					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit				

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

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

Pricing Considerations

4.3 The submission requested the same approved ex-manufacturer price (AEMP) for DAPSOMED 50 mg as the existing listing for DAPSONE 25 mg. Therefore, the price/mg for DAPSOMED 50 mg will be half that compared to DAPSONE 25 mg.

Drug cost/patient/year: \$1199

4.4 The Secretariat estimated the drug cost/patient/year would be \$1199, based on a dispensed price for maximum quantity (DPMQ) of \$328.45 and 3.65 scripts per year.

Estimated PBS usage and financial implications

4.5 The submission estimated a net save to the PBS/RPBS based on 50 mg being the TGA approved starting dose for dapsone and the price/mg of DAPSOMED 50 mg being half that compared to DAPSONE 25 mg. The volume of scripts for DAPSONE 25 mg is predicted to decrease as DAPSOMED 50 mg gains market share. A completed utilisation and cost model workbook was provided with the pre-PBAC response, estimating a net saving of \$0 to < \$10 million in Year 1, increasing to \$0 to < \$10 million by Year 6 (with the proposed listing taking 30% of the market in Year 1 to 100% of the market by Year 6).

5 PBAC Outcome

5.1 The PBAC recommended a General Schedule Unrestricted Benefit listing of a new 50 mg strength of dapsone (Dapsomed®; hereafter referred to as DAPSOMED) under the same conditions as the currently listed strengths of dapsone and on a cost-minimisation basis to the 25 mg tablet (Link Medical Products Dapsone; hereafter referred to as DAPSONE).

5.2 The PBAC noted that the TGA considered DAPSOMED to be bioequivalent to DAPSONE.

5.3 The PBAC advised the equi-effective doses to be 1 tablet of DAPSOMED 50 mg = 2 tablets of DAPSONE 25 mg.

5.4 The PBAC noted that the pre-PBAC response estimated a net save to the PBS/RPBS of \$0 to < \$10 million in Year 1, increasing to \$0 to < \$10 million by Year 6 based on 50 mg being the TGA approved starting dose for dapsone and the price/mg of DAPSOMED

50 mg being half that compared to DAPSONE 25 mg. The PBAC considered the estimated net save was reasonable.

- 5.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because DAPSOMED is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over DAPSONE, 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 2022 for Pricing Pathway A were not met.
- 5.6 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 Add new item:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
DAPSONE					
dapsone 50 mg tablet, 100	NEW	1	100	1	Dapsomed®
Benefit type [new]: Unrestricted					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit				

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.