

14.13 Request for temporary PBS listings

1 Purpose

- 1.1 To seek PBAC advice on temporary PBS listing of an alternative brand of primidone 250 mg tablets.
- 1.2 The sponsor requested temporary listing of this brand to substitute for the currently listed brand of primidone which is impacted by a supply shortage.

2 Background

- 2.1 Primidone is listed on the PBS as an unrestricted benefit. The Product Information of the current PBS listed brand notes primidone is indicated for management of grand mal and psychomotor (temporal lobe) epilepsy and it is also of value in the management of focal or Jacksonian seizures, myoclonic jerks and akinetic attacks.
- 2.2 From 1 July 2018 to 30 June 2019, there were 14,278 services of primidone, with 61 per cent of services being for concessional patients.
- 2.3 On 15 August 2019, the sponsor advised that there will be a critical medicine shortage for primidone from 1 October 2019. The Therapeutic Goods Administration (TGA) website has published details of a shortage of primidone from 1 October 2019 to 31 July 2020 caused by manufacturing issues.
- 2.4 The same sponsor has obtained approval for the importation and supply of an alternative brand of primidone in Australia, which is currently marketed in New Zealand, under section 19A(1) of the *Therapeutic Goods Act 1989*. The approval expiry date is 31 August 2020.
- 2.5 The alternative brand is the same form and strength as the current listing. The sponsor has requested listing under the same conditions as the current listing.
- 2.6 The alternative brand is a smaller pack size. Currently, primidone is listed with a pack quantity of 200 and the pack quantity of the alternative brand is 100. The submission also requested a higher price per tablet. Currently the price per tablet is 26.46 cents (AEMP of \$52.92 divided by 200). The submission requested a price per tablet of [REDACTED] cents (requested AEMP of \$[REDACTED] divided by 100). The details of the request and the expected financial impacts are as follows:

Out of stock product	AEMP	19A product	19A expiry	Requested AEMP	Financial impact until 31 Aug 2020
Primidone, Tablet 250 mg, 200 pack, Mysoline®	\$52.92 (26.46 cents per tablet)	Primidone, Tablet 250 mg, 100 pack, APO-PRIMIDONE®	31 August 2020	\$[REDACTED] cents per tablet)	\$0.170 million

- 2.7 The PBAC was requested to advise whether the new brand of primidone should be listed at the requested price for the duration of the current section 19A(1) approval.
- 2.8 The PBAC was also requested to advise under section 101(4AACD) of the *National Health Act 1953*, whether in the Schedule of Pharmaceutical Benefits, Mysoline and APO-PRIMIDONE should be treated as equivalent to each other.

3 PBAC Outcome

- 3.1 The PBAC recommended the temporary listing of APO-PRIMIDONE on the PBS to address the current supply shortage.
- 3.2 The PBAC considered there is a clinical need to maintain supply of this medicine on the PBS. The PBAC considered the listing should remain during the validity of the Section 19A(1) approval by the TGA.
- 3.3 The PBAC considered that the listing should be under the same conditions as the PBS listed product.
- 3.4 The PBAC considered that the price premium requested was appropriate, however advised that this should only exist for the duration of current Section 19A(1) approval, which lapses on 31 August 2020. Following the end of this current Section 19A(1) approval, any request to maintain the higher price would require a minor submission to the PBAC to justify the price requested.
- 3.5 The PBAC advised that this temporary listing should be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution at the pharmacy level.

4 Recommended listing

- 4.1 Add new item with identical restriction wording to the originator brand, Mysoline.

5 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.

6 Sponsor's Comment

The sponsor had no comment.