14.2 BENZTROPINE MESYLATE solution for injection 2 mg/2 mL vial Benztropine Omega®, A Menarini Australia Pty Ltd

1 Purpose of Application

1.1 To request an unrestricted benefit listing of an alternative brand (Benztropine Omega®) on the PBS in the General Schedule and Prescriber Bag.

2 Background

2.1 The PBAC recommended listing of Benztropine Omega at its November 2013 meeting, at a higher price than the Cogentin® brand of benztopine injection, due to a supply shortage of the Cogentin® brand of benztropine.

2.2 Benztropine Omega® was delisted in the first half of 2015.

3 Consideration of the evidence

3.1 The sponsor advised the Department of the short supply situation with Cogentin injections. The sponsor also advised that it had identified a supplier of benztropine injection in Canada and could supply this alternative product under Section 19A of the Therapeutic Goods Act. The alternative product was only available in a pack of 10 vials (compared with Cogentin, which is a pack of 5 vials).

3.2 The sponsor proposed an unrestricted benefit listing in the General Schedule and Prescriber Bag sections of the Schedule, in line with the listing of Cogentin, but with a maximum quantity of 1 pack of 10 ampoules and no repeats,.

3.3 Benztropine is used for the emergency treatment of acute dystonic reactions.

4 PBAC Outcome

4.1 The PBAC recommended listing of the proposed alternative brand of benztropine injection with the greater maximum quantity of 1 pack of 10 ampoules.

4.2 The PBAC noted that this recommendation re-affirmed the Committee's advice to the Minister in November 2013, following a similar request due to supply issues.

4.3 The PBAC re-affirmed their view that a clinical need exists for benztropine injection, and that it was desirable that it remain available on the PBS for the treatment of acute dystonic reactions.

4.4 The PBAC considered that the listing should be the same as the previous listing of Benztropine Omega and under the same conditions as the Cogentin

listing, and that the listing will remain during the validity of the Section 19A approval by the TGA.

4.5 The PBAC noted that the requested price for the alternative brand was higher than the current price for Cogentin, but at the same ex-manufacturer price as submission recommended in November 2013 submission.

Outcome:
Recommended

5 Recommended listing

5.1 Add the following new item in the General Schedule (Medical/Nurse practitioners and Dental) and Prescriber Bag (Medical/Nurse practitioners) sections of the Schedule.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
BENZTROPINE				
Benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL ampoule	1	0	Benztropine Omega	FK

6 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.

7 Sponsor's Comment

The sponsor had no comment.