6.10 BRIVARACETAM, Oral solution 10 mg per mL, 300 mL, Briviact®, UCB Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission sought PBAC advice to inform the Minister's consideration of whether brivaracetam oral solution 10 mg per mL, 300 mL (Briviact®) may be considered as an exempt item under subsection 84AH of the *National Health Act 1953* (the Act).

2 Background

Exempt item legislation

2.1.1 Where a submission has requested PBAC advice to inform the Minister's consideration to determine whether a pharmaceutical item may be an 'exempt item' under section 84AH of the Act, the PBAC must advise the Minister, under subsection 101(4AB) of the Act, whether the section 84AH(d) circumstances exist for that pharmaceutical item.

Pharmaceutical item

2.2 Section 84AB of the Act defines a pharmaceutical item as a declaration:

- in relation to a drug or medicinal preparation (the drug);
- in relation to a form of the drug; and
- in relation to a manner of administration of that form of the drug.

2.3 A form in this context is described in section 85 which states "the Minister may, by legislative instrument, determine, by reference to strength, type of unit, size of unit or otherwise, the form or forms of a listed drug".

Section 84AH

2.4 Section 84AH of the Act provides that the Minister may, by legislative instrument, determine a pharmaceutical item to be an exempt item if:

(a) there is only one listed brand of the relevant item; and

(b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and

(c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and

(d) the Minister is satisfied, having regard to advice (if any) given to the Minister by the Pharmaceutical Benefits Advisory Committee (whether before or after the commencement of this section), that:

i. the listed drug in the relevant item represents suitable therapy for a particular patient population; and

ii. the relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item; and

iii. no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

Section 101(4AB)

2.5 Under subsection 101(4AB) of the Act, the Committee must advise the Minister if these circumstances exist in relation to the pharmaceutical item:

(a) the listed drug in the pharmaceutical item represents suitable therapy for a particular patient population;

(b) the pharmaceutical item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item;

(c) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

Therapeutic Goods Administration (TGA) registration

2.6 Brivaracetam tablets and oral solution were TGA registered on 4 August 2016 as "add-on therapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 4 years of age with epilepsy".

PBAC considerations & PBS listing

2.7 The PBAC first considered brivaracetam tablets and oral solution at its July 2016 and March 2017 meetings before recommending listing at its November 2017 meeting.

2.8 Brivaracetam 25 mg, 50 mg, 75 mg and 100 mg tablets, and 10 mg per mL, 300 mL oral solution PBS listed on 1 May 2018 as Authority Required (Streamlined) listings.

2.9 At its November 2019 meeting, the PBAC recommended removing the age-based population criterion and the clinical criterion that patients be maintained on two or more other anti-epileptic drugs in combination with brivaracetam. In addition to these changes, the PBS indication for all listings was updated to "treatment of intractable partial onset epileptic seizures" on 1 April 2020.

Pricing history

2.10 Once listed on the PBS, medicines are subject to statutory price reductions (SPRs) under Division 3A of Part VII of the Act. SPRs apply to the approved ex-manufacturer price (AEMP), that is, before markups and fees are applied. Anniversary SPRs are applicable to F1 items and occur on the fifth, tenth and fifteenth anniversary of the date that the drug was listed on the PBS except where a pharmaceutical item is

considered an exempt item under section 84AH of the Act. Where a pharmaceutical item is determined to be an exempt item, it is excluded from the fifteen-year Anniversary SPR, the first new brand SPR (F1 item moving to F2), and price disclosure reductions (F2 items). Exempt items are not exempt from the five- and ten-year Anniversary SPRs.

2.11 Brivaracetam has been listed on the PBS since May 2018 and incurred its 5-year anniversary SPR (5% reduction) on 1 April 2024.

3 Eligibility for exempt status

3.1 The submission requested PBAC advice to inform the Minister's consideration to determine whether brivaracetam oral solution may be an 'exempt item' under section 84AH of the Act. Brivaracetam is PBS listed in 2 forms as separate pharmaceutical items, although both contain the same drug (brivaracetam) and have the same manner of administration (oral). Table 1 provides the section 84AH(a) to (c) criteria for context. Table 2 sets out the circumstances the PBAC must consider under subsection 101(4AB).

Table 1: Section 84AH(a-c)

The Act	Brivaracetam oral solution
s84AH (a): There is only one listed brand of the relevant item	Briviact is the only PBS listed brand of the oral solution form.
s84AH (b): There are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item	There are no PBS listed bioequivalent or biosimilar pharmaceutical items and therefore no listed brands. There are no listed biosimilars as none of the brivaracetam listings are biological in nature.
s84AH (c): The relevant item and at least one listed brand of another pharmaceutical item have the same drug	Both Briviact oral solution and Briviact tablet (across all strengths) have brivaracetam and are PBS listed.

Table 2: Section 84AH(d) / s101(4AB)

The Act	Brivaracetam oral solution
s84AH (d)(i) / s101(4AB)(a): The listed drug in the relevant item represents suitable therapy for a particular patient population	The TGA registered brivaracetam as a suitable "add-on therapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 4 years of age with epilepsy" in 2016. At its November 2017 meeting, the PBAC recommended brivaracetam as a suitable therapy for the treatment of intractable focal onset seizures.
s84AH (d)(ii) / s101(4AB)(b): The relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item	Brivaracetam oral solution is suitable for use by a particular subgroup of the population. The oral solution form of brivaracetam allows accurate weight-based dosing for children from 4 years of age or adolescents weighing less than 50 kg. Brivaracetam tablets are available in 25 mg, 50 mg, 75 mg and 100 mg strengths. The TGA PI states "the film-coated tablets must be taken orally whole with liquid". As such, a dose of 17.5 mg could not be delivered accurately without carefully cutting or crushing any of the existing tablet strengths and impairing the effectiveness of the film coating.
s84AH (d)(iii) / s101(4AB)(c): No other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item	Brivaracetam oral solution is appropriate for use in subgroups who are unable to swallow tablets. The current PBS restriction for the oral solution form contains a clinical criterion which states "Patient must be unable to take a solid dose form of this drug".

Sponsor hearing

3.2 There was no hearing for this item.

Consumer inputs

3.3 The PBAC noted that no consumer inputs were received for this item.

4 PBAC Outcome

4.1 The PBAC advised, under subsection 101(4AB) of the *National Health Act 1953*, that it considered the circumstances noted in section 84AH(d) of the Act exist for brivaracetam oral solution 10 mg per mL, 300 mL. The PBAC considered:

a) Brivaracetam oral solution represents suitable therapy for the treatment of intractable focal onset seizures.
b) Brivaracetam oral solution is suitable for use by a particular subgroup who require accurate weight-based dosing or who cannot swallow tablets, as existing tablet strengths cannot be cut or crushed to deliver accurate weight-based dosing.

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c) Brivaracetam tablets are not suitable for use by that particular subgroup because of the form of administration.

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

Outcome:
Advice provided

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

UCB Australia welcomes the PBAC's advice that brivaracetam oral solution, 10 mg per mL, 300 mg (Briviact®) is considered an exempt item under Section 84AH of the *National Health Act 1953*.

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