

6.14 CEFUROXIME
oral suspension, 125 mg per 5 mL, 100 mL;
tablets, 250 mg, 20,
Zinnat®, Aspen Pharmacare Pty Ltd.

1 Purpose of application

- 1.1 The minor submission sought the listing of the following:
1. A new pack size for the currently listed pharmaceutical item cefuroxime, tablet 250 mg (as axetil).
 2. A new pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL
- 1.2 The minor submission also requested PBAC provide advice to the Minister, under Section 101(4AB) of the *National Health Act 1953* (the Act), in relation to the new pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL. This advice will be relevant to the Minister making a determination under Section 84AH regarding exempt items.

2 Background

New pack size for cefuroxime tablets

- 2.1 Cefuroxime, tablet 250 mg (as axetil) is currently listed on the PBS as a 14-tablet pack.
- 2.2 The sponsor has indicated its intention to replace the current pack size to a 20-pack due to a change in the availability of the product from global overseas supplier. Cefuroxime, tablet 250 mg (as axetil) 20-pack was registered by the TGA on 26 August 2015.
- 2.3 The TGA Product Information (PI) outlines that the usual course of therapy with cefuroxime tablets is 5 – 7 days for treatment of bronchitis (250 mg to 500 mg twice daily), and 7 to 10 days for other infections (250 mg twice daily). The 20-pack will be consistent with the PI's guidelines for usual course of therapy for the treatment of non-bronchitis related 'other infections' such as otitis media, sinusitis, tonsillitis and pharyngitis.

New pharmaceutical item for cefuroxime oral suspension

- 2.4 Cefuroxime oral suspension (Zinnat® oral suspension) is currently listed on the PBS as the pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL.
- 2.5 The sponsor has indicated its intention to replace the current presentation with the pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL.

- 2.6 The TGA PI outlines that the usual course of therapy with Zinnat® suspension is 7 days (with a range of 5 to 10 days). The new pharmaceutical item will provide a consistent amount with the PI's guidelines for usual course of therapy for the treatments of otitis media, tonsillitis, pharyngitis.

Exemption request

- 2.7 The pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL, is currently listed with an exempt status.
- 2.8 The sponsor has indicated its intention to delist the current pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL, within 12 months after the listing of the 100 mL presentation.
- 2.9 The sponsor has requested the Minister to determine the new pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL as replacement of the currently exempted 70 mL presentation.
- 2.10 The sponsor further recognised that an interim period will apply whereby both presentations (70 mL and 100 mL) will be listed concurrently on the PBS where the exempt status will not apply to either presentations.
- 2.11 The Minister may, by legislative instrument, determine a pharmaceutical item to be an exempt item if it meets the following criteria set out in Section 84AH of the Act:
- 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.
- 2.12 The PBAC's function relating to the Minister's determination of exempt items, reflected under Section 101(4AB) of the Act, is the same as those in Section 84AH (d) as described above.
- 2.13 The effect of a pharmaceutical item being determined to be an exempt item is that the listed brand of that pharmaceutical item is excluded from statutory price reductions and price disclosure requirements.
- 2.14 The Revised Explanatory Memorandum of the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007* details that the intention of exemption is to encourage the availability of certain pharmaceutical items with particular

formulations of drugs that are used by a demographic subgroup (e.g. children or geriatric patients) for whom other formulations of the drug are not suitable. The Explanatory Memorandum clarifies that subgroups identified on the grounds of their disease characteristics will not qualify.

3 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

4 PBAC Outcome

- 4.1 The PBAC recommended the listing of a new pack size of 20 for the currently listed pharmaceutical item cefuroxime, tablet 250 mg (as axetil).
- 4.2 The PBAC recommended the listing of a new pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL.
- 4.3 The PBAC noted a small net cost to the PBS as a consequence of the reduction in repeat scripts which patients will no longer require because of the larger presentation for both tablets and suspension.
- 4.4 The PBAC advised, that in accordance with Section 101(4AB) of the Act, the following circumstances exist in relation to the pharmaceutical item cefuroxime, powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL:
- a) It represents suitable therapy for the treatment of the following:
 - mild to moderately severe infections caused by sensitive bacteria;
 - tonsillitis and pharyngitis; and
 - acute bacterial otitis media.
 - b) It is suitable for use by a particular subgroup being paediatric patients 3 months to 12 years of age.
 - c) Following the withdrawal of the 70 mL presentation from the PBS, no other pharmaceutical item that has this drug is suitable for use by paediatric subgroup because of either or both of the form and manner of administration of this drug within the other forms.

Outcome:

Recommended

5 Recommended listing

- 5.1 Add new items:

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Name, Restriction, Manner of administration and form	Max. Qty packs	No. of Rpts	Proprietary Name and Manufacturer	
CEFUROXIME CEFUROXIME AXETIL POWDER FOR ORAL SUSPENSION 125 MG (BASE) PER 5 ML, 100 ML	1	1	Zinnat	Aspen (AS)

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners

Name, Restriction, Manner of administration and form	Max. Qty packs	No. of Rpts	Proprietary Name and Manufacturer	
CEFUROXIME CEFUROXIME AXETIL POWDER FOR ORAL SUSPENSION 125 MG (BASE) PER 5 ML, 100 ML	1	0	Zinnat	Aspen (AS)

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Dental

Name, Restriction, Manner of administration and form	Max. Qty packs	No. of Rpts	Proprietary Name and Manufacturer	
CEFUROXIME CEFUROXIME 250 MG TABLET, 20	1	1	Zinnat	Aspen (AS)

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners

Name, Restriction, Manner of administration and form	Max. Qty packs	No. of Rpts	Proprietary Name and Manufacturer	
CEFUROXIME CEFUROXIME 250 MG TABLET, 20	1	0	Zinnat	Aspen (AS)

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Dental

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

Two new presentations (100 mL suspension & 20's tablets) are intended to replace the current 70 mL and 14's tablet presentations. For an interim period both (70 mL & 14's) presentations will be PBS listed to facilitate the drawing down of current stock levels. The 70 mL suspension and 14's tablet will be deleted in approximately 12 months after launch of 100 mL suspension and 20 tablet presentations.