6.18 RILUZOLE, Oral suspension 50 mg per 10 mL, 300 mL, Teglutik®, Asteri Pharma Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission sought PBAC advice on whether riluzole oral suspension (riluzole suspension) 50 mg per 10 mL, 300 mL (Teglutik®) is eligible to be considered as an exempt item under section 84AH of the *National Health Act 1953* (the Act).

2 Background

2.1 An exempt item under s84AH of the Act is exempt from the 15-year Anniversary Price Reduction, First New Brand Statutory Price Reduction, and Price Disclosure Reductions. Exempt items are not exempt from 5- and 10-year Anniversary Price Reductions.

2.2 Riluzole suspension is currently listed on the PBS as an Authority Required, General Schedule listing for the treatment of amyotrophic lateral sclerosis (ALS).

2.3 At present, the restriction criteria of the suspension and tablet form listings are the same.

Exempt item criteria under section 84AH of the Act

2.4 A pharmaceutical item in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* is the combination of the listed drug, form, and manner of administration. That is, where one of the drug, form, or manner of administration differ, this comprises a different pharmaceutical item.

2.5 For riluzole suspension to be determined as an 'exempt item' under section 84AH of the Act, the Minister may, by legislative instrument, determine it 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 PBAC, 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.

2.6 The Revised Explanatory Memorandum of the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007* states that the intention of this provision is to provide exemptions for particular formulations of drugs (eg, an oral solution) used by a demographic subgroup (eg, children or geriatric persons) for whom other formulations of that drug are not appropriate (eg, because they cannot swallow tablets). The patient subgroups will be demographically based, not disease based. Thus, highly specialised drugs with a small patient population will not qualify for an exemption; rather, exemptions may apply only to particular formulations of drugs that are otherwise more generally available.[1]

Registration status

2.7 Riluzole suspension was TGA registered on 1 August 2018 for the treatment of ALS.

Previous PBAC consideration

2.8 The PBAC has not previously considered this type of request in relation to riluzole suspension.

2.9 In November 2018, the PBAC recommended listing riluzole suspension for the treatment of ALS on a cost minimisation basis with riluzole tablets, with a price premium as this form of riluzole offers an advantage to some patients with this disease. The PBAC considered that a premium of 5-10% per mL for the liquid formulation over the tablet formulation would be reasonable (paragraph 7.1, riluzole Public Summary Document (PSD), November 2018 PBAC Meeting).

3 Consideration of the evidence

Sponsor hearing

3.1 There was no hearing for this item.

Consumer comments

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

[1] National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 - Revised Explanatory Memorandum, pg. 7.

Rationale of exempt item eligibility

3.3 Table 1 outlines the submission rationale for exempt item eligibility.

Table 1: Submission rationale for exempt item eligibility

Section 84AH Criteria	Teglutik (PBS item 11662T (initial) and 14429K (continuing)
(a) there is only one listed brand of the relevant item; and	Teglutik is the only listed brand of riluzole suspension, PBS item 11662T (initial) and 14429K (continuing).
(b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and	There are no pharmaceutical items on the PBS that the TGA or PBAC have explicitly considered to be bioequivalent or biosimilar to riluzole suspension. At its November 2018 meeting, the PBAC noted differences in the pharmacokinetic profile of riluzole liquid and tablets (paragraph 7.5, riluzole PSD, November 2018 PBAC Meeting).
(c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and	Riluzole suspension and riluzole tablet 50 mg (Pharmacor® Riluzole; Rilutek®; Riluzole Sandoz®) share the same drug.
(d) advice (if any) given by the PBAC, that: (i) the listed drug represents suitable therapy for a particular patient population; and	The submission stated that riluzole suspension represents a suitable therapy for ALS patients.
(d) advice (if any) given by the PBAC, that: (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	The submission stated that, due to being a liquid form, riluzole suspension is suitable for ALS patients who experience dysphagia (impairment of swallowing) and/or who require percutaneous endoscopic gastrostomy (PEG) tube administration where the use of tablets is difficult and may lead to choking.
(d) advice (if any) given by the PBAC, that: (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.	The only other pharmaceutical item that contains riluzole is riluzole tablet 50 mg. The submission claimed that for ALS patients with dysphagia and/or requiring PEG tube administration, the tablet formulation is not suitable because administration in such patients often involves crushing tablets and mixing with liquid/food, which it characterised as a sub-optimal alternative to riluzole suspension. The submission stated that, in the absence of the oral suspension, patients with swallowing difficulties may need to crush tablets, which it described as outside the intended use and potentially affecting absorption and dosing accuracy. It described tablet crushing as potentially unsafe and less accurate, citing issues including unpleasant local anaesthetic effects when tablets are crushed, carer/healthcare worker exposure to drug dust, dose loss/underdosing (including reported loss of active ingredient powder in a simulated at-home study), and micro-aspiration/respiratory infection risk (and potential PEG tube issues). The submission described riluzole suspension as a ready-to-use, bioequivalent alternative to the tablet, with accurate dosing and safer administration, designed for use in patients with dysphagia and/or who require PEG tube administration. The submission referenced the PBAC's November 2018 consideration that there was a clinical need for an alternative form to the tablet, which is often difficult to administer in these patients, and that the suspension form offers an advantage to such patients (para 7.2, riluzole PSD, Nov 2018 PBAC Meeting). The PBAC is asked to advise if the tablet form of riluzole is not suitable, less suitable, or equally suitable for ALS patients with dysphagia and/or who require PEG tube administration.

Source: Table 2 of submission as well as the submission main body (sections 3,4 and 5).

Financial considerations

3.4 The restrictions for both the tablet and suspension forms do not prevent switching between formulations. Supply data indicate that the tablet form was used more frequently than the suspension, with [redacted] supplies ([redacted]%) of the tablet and [redacted] supplies ([redacted]%) of the suspension in 2025, and an average of [redacted] ([redacted]%) tablet supplies and [redacted] ([redacted]%) suspension supplies per year between 2020 and 2025. Switching between formulations also occurred in both directions, although more frequently from tablet to suspension than vice versa; in 2025 there were [redacted] switches from tablet to suspension compared with [redacted] from suspension to tablet, and between 2020 and 2025 the average number of switches per year was [redacted] from tablet to suspension and [redacted] from suspension to tablet.

4 PBAC Outcome

4.1 The PBAC advised under subsection 101(4AB) of the Act that it is of the opinion that the circumstances of the riluzole suspension listing meet the eligibility criteria under section 84AH of the Act.

4.2 The PBAC advised that riluzole suspension remained a suitable therapy for ALS patients, including a subgroup of patients who experience swallowing difficulties and/or require PEG tube administration. The PBAC considered that the tablet form is less suitable for this subgroup because administration may require tablet crushing, which it considered to be sub-optimal and may affect dosing accuracy and administration. In the context of a PBS-listed oral suspension for the same patient population, the PBAC considered the tablet form did not represent a suitable listed alternative pharmaceutical item for that subgroup.

4.3 The PBAC therefore considered that the criteria for eligibility were met, noting that:

- Teglutik is the only listed brand of riluzole suspension and that there are other listed pharmaceutical items that contain riluzole (Pharmacor® Riluzole; Rilutek®; Riluzole Sandoz®).
- The PBAC considered that no other listed pharmaceutical item is bioequivalent, biosimilar or 'a'-flagged to riluzole suspension.

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

The sponsor had no comment.