# 5.25 PREGABALIN, Oral solution 20 mg per mL, 473 mL, Pregabalin-AFT®, AFT Pharmaceuticals (AU) Pty Ltd

## 1 Purpose of item

1.1 The Category 4 submission sought an Authority Required (STREAMLINED) listing for pregabalin 20 mg per mL oral liquid (herein referred to as Pregabalin-AFT®) under the same conditions as the currently PBS-listed pregabalin capsules for neuropathic pain.

## 2 Background

2.1 Pregabalin-AFT was TGA registered on 16 September 2020 for the treatment of neuropathic pain in adults and as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

2.2 The PBAC has not previously considered a submission for pregabalin oral solution.

2.3 Pregabalin capsules are currently listed on the PBS under the General Schedule as an Authority Required (STREAMLINED) listing for neuropathic pain.

## 3 Requested listing

3.1 The submission requested that Pregabalin-AFT be listed under the same circumstances as pregabalin capsules (2348N, 2335X, 2355Y and 2363J).

3.2 The new medicinal product pack is shown in italics.

| MEDICINAL PRODUCT<br>Medicinal Product Pack | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|---|---|---|---|---|---|
| *PREGABALIN*<br><br>*Pregabalin 20 mg/mL oral liquid, 473 mL* | New | 1 | 1 | 5 | Pregabalin-AFT |

3.3 The dose range for pregabalin for neuropathic pain according to the Product Information, is 150 to 600 mg (7.5 to 30 mL) per day given in two divided doses. Each prescription will provide 63 days of treatment for a patient on a daily dose of 150 mg (7.5 mL) or 15 days of treatment for a patient on a daily dose of 600 mg (20 mL). The maximum quantity and number of repeats are appropriate.

## 4 Comparator

4.1 The submission nominated the currently listed pregabalin capsules as the main comparators. This was appropriate.

4.2 The submission noted that TGA considered Pregabalin-AFT to be bioequivalent to the currently listed brand of pregabalin capsules, LYRICA 25 mg, 75 mg, 150 mg and 300 mg.

4.3 The submission claimed that the new formulation allows flexibility and convenience for dose titration when required and provides an alternative for patients with difficulties swallowing pregabalin capsules.

# 5 Consideration of the evidence

## *Sponsor hearing*

5.1 There was no hearing for this item.

## *Consumer comments*

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

## *Pricing consideration*

5.3 The submission requested listing Pregabalin-AFT on a cost-minimisation basis to pregabalin capsules. The sponsor proposed an approved ex-manufacturer price (AEMP) of $[redacted] for Pregabalin-AFT. This is equivalent to $[redacted] per mg. The submission claimed that an AEMP of $[redacted] provides a lower cost per treatment compared to pregabalin 25 mg and 75 mg capsules which account for the majority of the script volume. A cost comparison of Pregabalin-AFT and the currently listed pregabalin capsules based on the average recommended dose of 150 mg twice daily is summarised below. The pre-PBAC Response stated the Sponsor was not able to propose a lower AEMP which would provide a lower cost per treatment compared to 150 mg and 300 mg capsules.

**Table 1: Cost comparison across PBS Listed products**

| | Pack size | Price per pack (AEMP) ($) | Price per mg ($) | Price per 300 mg treatment ($) | Treatment days per pack size based on 300 mg dose | PBS total scripts per year (2020) |
|---|---|---|---|---|---|---|
| **Sponsor Product** | | | | | | |
| Pregabalin-AFT Oral Liquid, 20 mg/mL | 473 mL | [redacted] | [redacted] | [redacted] | 31.53 | N/A |
| **Comparative Product** | | | | | | |
| 25 mg capsules | 56 capsules | $3.73 | $0.002664 | $0.80 | 4.67 | 906,431 |
| 75 mg capsules | 56 capsules | $8.25 | $0.001964 | $0.59 | 14.00 | 1,246,705 |
| 150 mg capsules | 56 capsules | $12.66 | $0.001507 | $0.45 | 28.00 | 784,908 |
| 300 mg capsules | 56 capsules | $18.88 | $0.001124 | $0.34 | 56.00 | 405,599 |

Source: Table 2, p4 of the submission.

## *Estimated PBS utilisation and financial implications*

5.4 The submission used a market share approach to estimate the uptake and financial implications of Pregabalin-AFT. The submission stated that Pregabalin-AFT is not expected to increase market size or growth and that only a fraction of patients will switch from using capsules to oral liquid.

5.5 The submission predicted that Pregabalin-AFT will substitute for 1% of pregabalin capsules within the first year of listing, increasing to 5% by the sixth year.

5.6 The submission estimated that the net financial impact to the PBS/RPBS will be a net save of $0 to < $10 million in Year 6 of listing, with a total net save to the PBS/RPBS of $0 to < $10 million over the first 6 years of listing. As the proposed price for Pregabalin-AFT is only lower compared to 25 mg and 75 mg pregabalin capsules, the estimated net save is dependent on the substitution rate of 25 mg and 75 mg capsules versus

150 mg and 300 mg capsules. The pre-PBAC Response indicated that the substitution rate of 300 mg capsules was potentially lower than that in the financial estimates because these pack sizes are generally prescribed for patients requiring a higher dose of 600 mg per day. The pre-PBAC Response noted that a lower substitution rate of 300 mg capsules would result in more cost-savings to the PBS.

**Table 2: Estimated use and financial implications**

| | Year 1 (2022) | Year 2 (2023) | Year 3 (2024) | Year 4 (2025) | Year 5 (2026) | Year 6 (2027) |
|---|---|---|---|---|---|---|
| **Estimated extent of use** | | | | | | |
| Number of Pregabalin-AFT Oral Liquid scripts dispensed[a] | [redacted][1] | [redacted][2] | [redacted][3] | [redacted][4] | [redacted][5] | [redacted][5] |
| **Drug costs to PBS** | | | | | | |
| Cost of Pregabalin-AFT Oral Liquid to PBS | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Less co-payments | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Net cost to PBS | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| **Drug costs to RPBS** | | | | | | |
| Cost of Pregabalin-AFT Oral Liquid to RPBS | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Less co-payments | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Net cost to RPBS | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| **Cost of affected PBS/RPBS listings** | | | | | | |
| Pregabalin 25 mg 2348N | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Pregabalin 75 mg 2335X | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Pregabalin 150 mg 2355Y | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Pregabalin 300 mg 2363J | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Less patient co-payments | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| Total | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |
| **Net financial implications** | | | | | | |
| Net cost to PBS/RPBS | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] | [redacted][6] |

[a] Assuming 11.58 scripts per patient per year as estimated by the submission. The submission assumed that up to 5% of market share could be switched from pregabalin capsules to Pregabalin-AFT Oral Liquid.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Table 3, p5 of the submission, Excel workbook 'Appendix 2 – UCM-Release-3Workbook-v108 for PREGABALIN-AFT OL.xlsc'

*The redacted values correspond to the following ranges:*

*[1] 20,000 to < 30,000*

*[2] 40,000 to < 50,000*

*[3] 60,000 to < 70,000*

*[4] 80,000 to < 90,000*

*[5] 100,000 to < 200,000*

*[6] $0 to < $10 million*

5.7 As a Category 4 submission, neither the economic analysis nor the financial estimates analysis have been independently evaluated.

# 6 PBAC Outcome

6.1 The PBAC deferred making a recommendation about the PBS-listing of pregabalin 20 mg per mL oral liquid (Pregabalin-AFT) for the treatment of neuropathic pain to allow for utilisation analysis of the currently listed immediate release pregabalin capsules and to further consider potential quality use of medicines issues with Pregabalin-AFT.

6.2 The PBAC was concerned about reports of potential misuse and diversion of pregabalin (and gabapentinoids more broadly) in Australia. The Committee therefore considered it was prudent to review the utilisation of pregabalin and consider any current evidence of misuse and diversion in Australia prior to forming a view as to whether additional forms of pregabalin should be recommended for listing on the PBS.

The PBAC referred the matter of pregabalin use to the Drug Utilisation Sub-Committee (DUSC) for consideration at a future meeting.

6.3 The PBAC noted the submission's claim that an oral liquid formulation of pregabalin would provide flexibility for dose titration and an alternative presentation for patients with swallowing difficulties. The PBAC was uncertain of the clinical need for an oral liquid formulation of pregabalin, noting the contents of pregabalin capsules could be dispersed in water or food for people with swallowing difficulties. The PBAC considered that input from clinicians and consumers would assist in determining the clinical need for a liquid formulation of pregabalin.

6.4 The PBAC considered that there was a potential for market growth if Pregabalin-AFT was listed on the PBS as there may be patients not currently on pregabalin capsules who would utilise an oral liquid formulation.

**Outcome:**
Deferred

# 7 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.

# 8 Sponsor's Comment

The sponsor had no comment.