5.20 BREXPIPRAZOLE, Tablet 500 micrograms, Rexulti®, Lundbeck Australia Pty Ltd

1 Purpose of Submission

1.1 To request a General Schedule Authority Required (STREAMLINED) listing of a new 0.5 mg strength of brexpiprazole tablet under the same circumstances as the existing PBS-listed strengths of brexpiprazole tablet.

2 Background

2.1 Brexpiprazole (as tablet 1 mg, 2 mg, 3 mg and 4 mg) is currently listed on the PBS as an Authority Required (STREAMLINED) listing for the treatment of schizophrenia.

Registration status

2.2 Brexpiprazole was TGA registered on 19 May 2017 for the treatment schizophrenia in adults.

Previous PBAC consideration

2.3 At its March 2017 meeting, the PBAC recommended brexpiprazole tablet (1, 2, 3 and 4 mg) for the treatment of schizophrenia and it was PBS listed on 1 October 2017.

2.4 Brexpiprazole 0.5 mg tablet has not been considered by the PBAC previously.

3 Requested listing

3.1 The submission requested the addition of the new strength with the same restriction wording as the existing PBS-listed strengths of brexpiprazole:

MEDICINAL PRODUCT **medicinal product pack**		**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
BREXPIPRAZOLE						
brexpiprazole 0.5 mg tablet, 30		NEW	1	30	0	Rexulti
Restriction Summary: 16004 / Treatment of Concept: 4246						
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners					
	Restriction type: ☒Authority Required (Streamlined)					
	Indication: Schizophrenia					

4 Comparator

4.1 The submission proposed the currently listed strengths of brexpiprazole as the comparator. The PBAC considered this appropriate.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted input from individuals (2) via the Office of Health Technology Assessment Consultation Hub. The PBAC noted that while the consumer inputs received were not directly related to the requested indication, they reflected lived experiences with brexpiprazole that some individuals considered relevant to the broader context of its use.

Justification of the requested listing

5.3 The submission noted that the TGA has only approved the use of brexpiprazole in adults and that safety and effectiveness in patients under the age of 18 years has not yet been evaluated (Appendix C). The TGA recommended starting dose for the treatment of schizophrenia in adults is 1 mg.

5.4 The submission stated that use of a 0.5 mg strength for dose titration is necessary for patients who require a less than 1 mg dose, because the tablet size of the listed strengths of brexpiprazole is too small to be scored and therefore cannot be split accurately. The submission considered that attempting to split a 1 mg tablet for dose titration presents a quality use of medicines issue by risking receiving an inaccurate dose.

Pricing considerations

5.5 The submission proposed flat pricing (i.e. same price per tablet) for the 0.5 mg strength, consistent with the pricing structure for the other existing PBS-listed strengths.

Estimated PBS usage and financial implications

5.6 An epidemiological approach was taken to estimate the financial implications of listing the 0.5 mg strength of brexpiprazole.

5.7 Table 1 presents the estimated extent of use and cost of brexpiprazole to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

5.8 The submission estimated that 500 to < 5,000 scripts would be supplied over the first six years of listing (< 500 in Year 1 to < 500 in Year 6).

5.9 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of brexpiprazole is $0 to < $10 million over six years (Year 1 $0 to < $10 million to Year 6 $0 to < $10 million).

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of patients treated	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Number of scripts dispensed[a]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of 0.5 mg tablet						
Cost to PBS/RPBS less co-payment	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Estimated financial implications of 1 mg, 2 mg, 3 mg and 4 mg tablet						
Cost to PBS/RPBS less co-payment	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]

[a] Assuming 1 per patient per year as estimated by the submission.
Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Worksheets 2a, 3a, 3b, 4b, 5 of the updated UCM Workbook (250605_PBAC_Section 4_REXULTI UCM Workbook_Updated.xlsx.)
The redacted values correspond to the following ranges:
[1] < 500
[2] $0 to < $10 million

5.10 At year 6, the estimated number of patients was <500and the net cost to the PBS would be $0 to < $10 million.

5.11 At year 1, the estimated number of patients was <500 and the net cost to the PBS would be $0 to < $10 million.

6 PBAC Outcome

6.1 PBAC recommended the listing of new form of brexpiprazole, tablet 500 micrograms, under the same circumstances as the current PBS-listed strengths of brexpiprazole tablet.

6.2 The PBAC noted the potency of brexpiprazole, the highest dose being only 4 mg, and acknowledged that the 0.5 mg strength would better facilitate dose titration in patients who require a less than 1 mg dose or who require a more gradual dose escalation.

6.3 The PBAC considered the proposed flat pricing approach, consistent with existing strengths, was reasonable.

6.4 During evaluation of the submission, revised utilisation estimates were sought, and the PBAC considered the revised estimates to be reasonable.

6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because brexpiprazole 0.5 mg tablet is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the other listed strengths of brexpiprazole, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

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

Outcome:
Recommended

7 Recommended listing

7.1 Add new item:

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	Restriction type: ☒Authority Required (Streamlined)				
	Indication: Schizophrenia				

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

9 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.

10 Sponsor's Comment

Lundbeck Australia welcomes the decision of the PBAC which recognises the need for reimbursed access to treatments for Australians living with serious mental illness.