

## 9.01 Review of low-cost PBS-listed antidepressants

### 1 Purpose of item

That the Pharmaceutical Benefits Advisory Committee (PBAC):

- 1.1 **Provide advice** on the proposed amendments to Pharmaceutical Benefits Scheme (PBS) restrictions for selected low-cost antidepressants.
- 1.2 **Provide advice** on the estimated financial impact of the proposed changes to the Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme (R/PBS).
- 1.3 **Note** the pre-PBAC responses.

### 2 Background

- 2.1 At its September 2023 meeting, as part of its consideration of the Post-market Review (PMR) workplan, the PBAC supported a proposal that the Department consider, on a rolling basis, whether medicines that have transitioned to the F2 formulary may be suitable for a review of their PBS restrictions. The PBAC noted that this work may support the Therapeutic Goods Administration's (TGA) Medicines Repurposing Program.
- 2.2 At its September 2024 meeting, the PBAC supported the Department's proposal to compile further information to inform consideration of whether Unrestricted Benefit listings may be appropriate for several low-cost PBS-listed antidepressants. The PBAC noted that for some Restricted Benefit listings, the TGA-approved indications are broader than the PBS-listed indications. In addition, Australian clinical guidelines recommend a wider range of uses beyond the PBS-listed and/or TGA-approved indication(s). The PBAC also noted that, because these medicines are generally low cost, there may be limited commercial incentive for sponsors to pursue TGA registration changes or submit applications to amend PBS restrictions.
- 2.3 In December 2025, the PBAC considered medicines used off-label or outside existing PBS listing arrangements identified by the National Aboriginal Community Controlled Health Organisation (NACCHO). As part of this consideration, the PBAC noted that duloxetine had been identified by NACCHO for broader subsidised access for neuropathies and agreed that duloxetine should be included in the upcoming low-cost medicine review (antidepressant tranche).
- 2.4 Accordingly, the Department undertook a review of selected low-cost PBS-listed antidepressants to:
  - compare current PBS restrictions with TGA-approved indications and Australian clinical guidelines;
  - identify medicines where current PBS restrictions may warrant further consideration in light of contemporary clinical practice; and
  - estimate the financial impact to the R/PBS of potential changes to PBS restrictions.

***Sponsor and stakeholder consultation***

- 2.5 On 20 August 2026, sponsors of the antidepressants included in this review and relevant clinical, consumer and First Nations organisations were provided with the PBAC overview paper and invited to provide a pre-PBAC response in line with standard PBAC processes and timelines. Organisations consulted included the Royal Australian and New Zealand College of Psychiatrists (RANZCP), the Royal Australian College of General Practitioners (RACGP), the Australian College of Rural and Remote Medicine (ACRRM), the Australian College of Nurse Practitioners (ACNP), NACCHO, the National Mental Health Consumers Alliance (NMHCA) and Mental Health Carers Australia (MHCA).

**3 Medicines under review and proposed PBS restriction changes*****Medicines considered in the review***

- 3.1 The review included selected PBS-listed antidepressants classified under Anatomical Therapeutic Chemical (ATC) code N06A (antidepressants) that are listed on the F2 formulary, are subject to Restricted Benefit listing arrangements and have a Dispensed Price for Maximum Quantity (DPMQ) generally lower than the PBS general patient co-payment (\$25). Although these medicines are generally low cost, private supply may still represent a higher out-of-pocket cost for some patients where use falls outside current PBS restrictions. This includes concessional patients, who would otherwise pay the PBS concessional co-payment (\$7.70), and patients who have reached the annual PBS Safety Net or eligible First Nations people registered for the Closing the Gap PBS Co-payment Program, who may receive their prescribed PBS medicines at no cost depending on concessional status.
- 3.2 The fourteen antidepressants included in the review, including PBS-listed strengths and forms and DPMQs, are summarised in Table 1. These medicines are predominantly mature generic antidepressants, with DPMQs for most tablet and capsule formulations ranging from approximately \$17 to \$24 for a standard 30-day supply. Mianserin 20 mg tablet had a higher 30-day DPMQ (\$30.32) but remained materially lower than several higher-cost antidepressants excluded from the review. Escitalopram oral liquid also had a higher DPMQ than the escitalopram tablet formulations, as shown in Table 1, as this form is exempt from certain legislated statutory price reductions under Section 84AH of the *National Health Act 1953*.

**Table 1: PBS-listed forms and DPMQs for included antidepressants**

| Medicine       | PBS-listed strength(s) and form(s) included                               | 30-day DPMQ range                       | 60-day DPMQ range                       |
|----------------|---------------------------------------------------------------------------|-----------------------------------------|-----------------------------------------|
| Citalopram     | 10 mg tablet; 20 mg tablet; 40 mg tablet                                  | \$17.10–\$17.14                         | \$19.84–\$19.92                         |
| Clomipramine   | 25 mg tablet                                                              | \$19.25                                 | N/A                                     |
| Desvenlafaxine | 50 mg tablet; 100 mg tablet                                               | \$21.09–\$22.62                         | \$27.82–\$30.88                         |
| Duloxetine     | 30 mg capsule; 60 mg capsule                                              | \$18.46–\$18.60                         | \$22.84                                 |
| Escitalopram   | 10 mg tablet; 20 mg tablet;<br>20 mg/mL oral liquid                       | Tablet: \$17.10<br>Oral liquid: \$39.55 | Tablet: \$19.84<br>Oral liquid: \$64.74 |
| Fluoxetine     | 20 mg tablet; 20 mg capsule                                               | \$18.10                                 | \$21.84                                 |
| Fluvoxamine    | 50 mg tablet; 100 mg tablet                                               | \$19.86–\$22.67                         | \$25.36–\$30.98                         |
| Mianserin      | 10 mg tablet; 20 mg tablet                                                | \$21.92–\$30.32                         | \$29.48–\$46.28                         |
| Mirtazapine    | 15 mg tablet; 15 mg ODT; 30 mg tablet; 30 mg ODT; 45 mg tablet; 45 mg ODT | \$17.33–\$21.22                         | \$20.30–\$28.08                         |
| Moclobemide    | 150 mg tablet; 300 mg tablet                                              | \$19.81–\$23.43                         | \$25.26–\$32.50                         |
| Nortriptyline  | 10 mg tablet; 25 mg tablet                                                | \$18.65–\$20.06                         | N/A                                     |
| Paroxetine     | 20 mg tablet                                                              | \$18.10                                 | \$21.84                                 |
| Sertraline     | 50 mg tablet; 100 mg tablet                                               | \$17.10                                 | \$19.84                                 |
| Venlafaxine    | 37.5 mg capsule; 75 mg capsule; 150 mg capsule                            | \$17.32–\$18.60                         | \$21.84–\$22.84                         |

Note: All medicines in Table 1 are currently listed on the F2 formulary and are subject to Restricted Benefit listing arrangements. DPMQ ranges reflect different strengths and/or formulations.

Abbreviations: DPMQ = Dispensed Price for Maximum Quantity; N/A = not applicable; ODT = orally disintegrating tablet; PBS = Pharmaceutical Benefits Scheme.

### 3.3 Current PBS indications, TGA-approved indications and Australian guideline indications for the included antidepressants are summarised in Table 2.

**Table 2: Current PBS, TGA-approved and Australian guideline indications for included antidepressants**

| Medicine       | Current PBS indication(s)                                               | TGA-approved indication(s)                                          | Australian guideline indication(s)                                                                                                                |
|----------------|-------------------------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Citalopram     | MD                                                                      | MD                                                                  | BD; BDD; BN; depression (dementia); GAD; MD; menopause (vasomotor symptoms); OCD; PD; PTSD; separation anxiety; SAD                               |
| Clomipramine   | Cataplexy associated with narcolepsy; OCD; phobic disorders in adults   | MD; OCD and phobias in adults; cataplexy associated with narcolepsy | BDD; MD; OCD; PD                                                                                                                                  |
| Desvenlafaxine | MD                                                                      | MD                                                                  | BDD; GAD; MD; menopause (vasomotor symptoms); OCD; PD; PTSD; SAD                                                                                  |
| Duloxetine     | MD                                                                      | MD; GAD                                                             | Neuropathic pain; BDD; fibromyalgia; GAD; MD; OCD; osteoarthritis; PD; PTSD; SAD                                                                  |
| Escitalopram   | MD; Moderate to severe GAD/SAD                                          | MD; SAD; GAD; OCD                                                   | BD; BDD; depression (dementia); GAD; MD; menopause (vasomotor symptoms); OCD; PD; PTSD; separation anxiety; SAD                                   |
| Fluoxetine     | MD; OCD                                                                 | MD; OCD                                                             | Binge eating disorder; BD; BDD; BN; GAD; MD; menopause (vasomotor symptoms); OCD; PD; PTSD; premature ejaculation; separation anxiety; SAD        |
| Fluvoxamine    | MD; OCD                                                                 | MD; OCD                                                             | BD; BDD; BN; GAD; MD; OCD; PD; PTSD; separation anxiety; SAD                                                                                      |
| Mianserin      | Severe depression                                                       | MD                                                                  | MD                                                                                                                                                |
| Mirtazapine    | MD                                                                      | MD                                                                  | Akathisia; GAD; tension headache; itch; MD; PTSD; cannabis withdrawal                                                                             |
| Moclobemide    | MD                                                                      | MD                                                                  | MD                                                                                                                                                |
| Nortriptyline  | MD (when other antidepressant therapy has failed or is contraindicated) | MD                                                                  | Neuropathic pain; faecal incontinence; fibromyalgia; functional GI disorders; tension headache; IBS; MD; migraine prophylaxis; smoking management |
| Paroxetine     | MD; OCD; PD                                                             | MD; OCD; PD; SAD; GAD; PTSD                                         | BD; BDD; GAD; itch; MD; menopause (vasomotor symptoms); OCD; PD; PTSD; premature ejaculation; SAD                                                 |
| Sertraline     | MD; OCD; PD                                                             | MD; OCD; PD; SAD; PMDD                                              | BD; BDD; BN; depression (dementia); GAD; itch; MD; OCD; PD; PTSD; premature ejaculation; separation anxiety; SAD                                  |
| Venlafaxine    | MD                                                                      | MD; GAD; SAD; PD                                                    | Neuropathic pain; tension headache; hot flushes (palliative care); menopause (vasomotor symptoms); PTSD; PD; GAD; OCD; BDD; SAD; MD               |

Note: PBS indications were sourced from the PBS website. TGA-approved indications were sourced from the relevant Product Information documents. Australian guideline indications were sourced from Therapeutic Guidelines: eTG complete, accessed 10 August 2026.

Abbreviations: BD = bipolar disorder; BDD = body dysmorphic disorder; BN = bulimia nervosa; GAD = generalised anxiety disorder; GI = gastrointestinal; IBS = irritable bowel syndrome; MD = major depression/major depressive disorder; OCD = obsessive-compulsive disorder; PBS = Pharmaceutical Benefits Scheme; PD = panic disorder; PMDD = premenstrual dysphoric disorder; PTSD = post-traumatic stress disorder; SAD = social anxiety disorder; TGA = Therapeutic Goods Administration.

- 3.4 For most of the included antidepressants, Australian clinical guidelines recommend use across a broader range of conditions than the current PBS indication(s), including mood, anxiety, obsessive-compulsive, pain-related and other conditions. For several medicines, TGA-approved indications were also broader than the current PBS indication(s). This suggested that indication-specific wording in the PBS restrictions may no longer reflect contemporary clinical practice and supported consideration of broadening PBS-subsidised access by removing indication-specific restriction wording.
- 3.5 Medicines listed on the PBS under ATC code N06A but excluded from the review are summarised in Table 3.

Table 3: Medicines excluded from the review

| Medicine              | Formulary | Rationale for exclusion                                                                                                                                                                                    |
|-----------------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Amitriptyline         | F2        | Already listed as an Unrestricted Benefit.                                                                                                                                                                 |
| Dosulepin (dothiepin) | F2        | Already listed as an Unrestricted Benefit.                                                                                                                                                                 |
| Esketamine            | F1        | F1 medicine and outside the primary scope of the review. Authority Required listing and substantially higher cost than the medicines included in the review.                                               |
| Imipramine            | F2        | Already listed as an Unrestricted Benefit.                                                                                                                                                                 |
| Lithium carbonate     | F1        | F1 medicine and outside the primary scope of the review. Not considered an antidepressant for the purposes of this review and has a substantially different clinical role from the medicines under review. |
| Phenelzine            | F1        | F1 medicine and outside the primary scope of the review. Associated with substantially higher DPMQs than the medicines included in the review (approximately \$215).                                       |
| Reboxetine            | F1        | F1 medicine and outside the primary scope of the review. Associated with higher DPMQs than the medicines included in the review (approximately \$40).                                                      |
| Tranylcypromine       | F2        | Already listed as an Unrestricted Benefit.                                                                                                                                                                 |

Abbreviations: DPMQ = Dispensed Price for Maximum Quantity.

### ***Proposed PBS restriction changes***

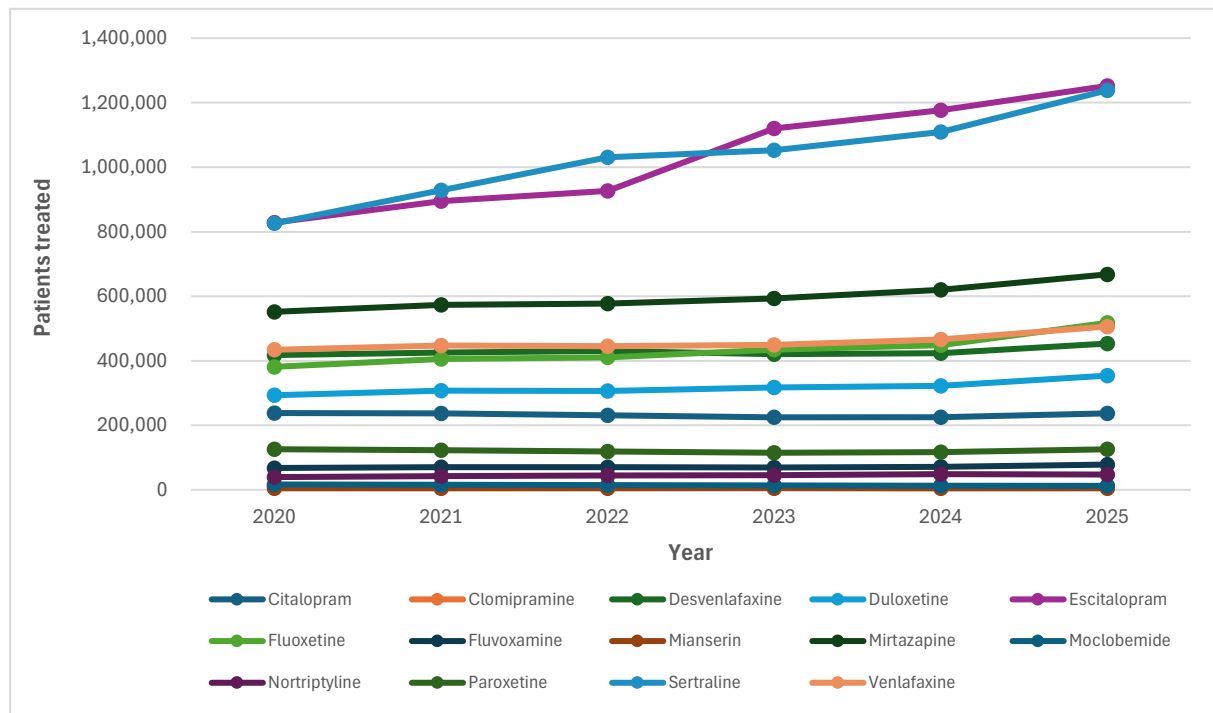
- 3.6 For the fourteen included antidepressants, the proposed changes to 30-day PBS listings involved amending the current Restricted Benefit listings to Unrestricted Benefit listings, with the indication and any eligibility criteria removed. For 60-day PBS listings, Restricted Benefit status was proposed to be retained; however, indication-specific wording would be removed and replaced with the existing clinical criterion, consistent with all similar 60-day listings, that 'the condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.'
- 3.7 The proposed changes were intended to remove indication-specific restriction wording and allow PBS-subsidised access to the included antidepressants for a broader range of conditions. This was expected to better accommodate contemporary clinical practice, where Australian clinical guidelines recommend use of many of these antidepressants across conditions beyond their current PBS indications.

## 4 Historical utilisation of included antidepressants

### R/PBS utilisation

- 4.1 The figures below present R/PBS utilisation of the included antidepressants between 2020 and 2025, including annual patient numbers, prescriptions supplied and R/PBS benefits paid by medicine.
- 4.2 Figure 1 shows the annual number of patients treated with each included antidepressant between 2020 and 2025, based on prevalent patient counts.

Figure 1: Patients treated with included antidepressants, 2020–2025

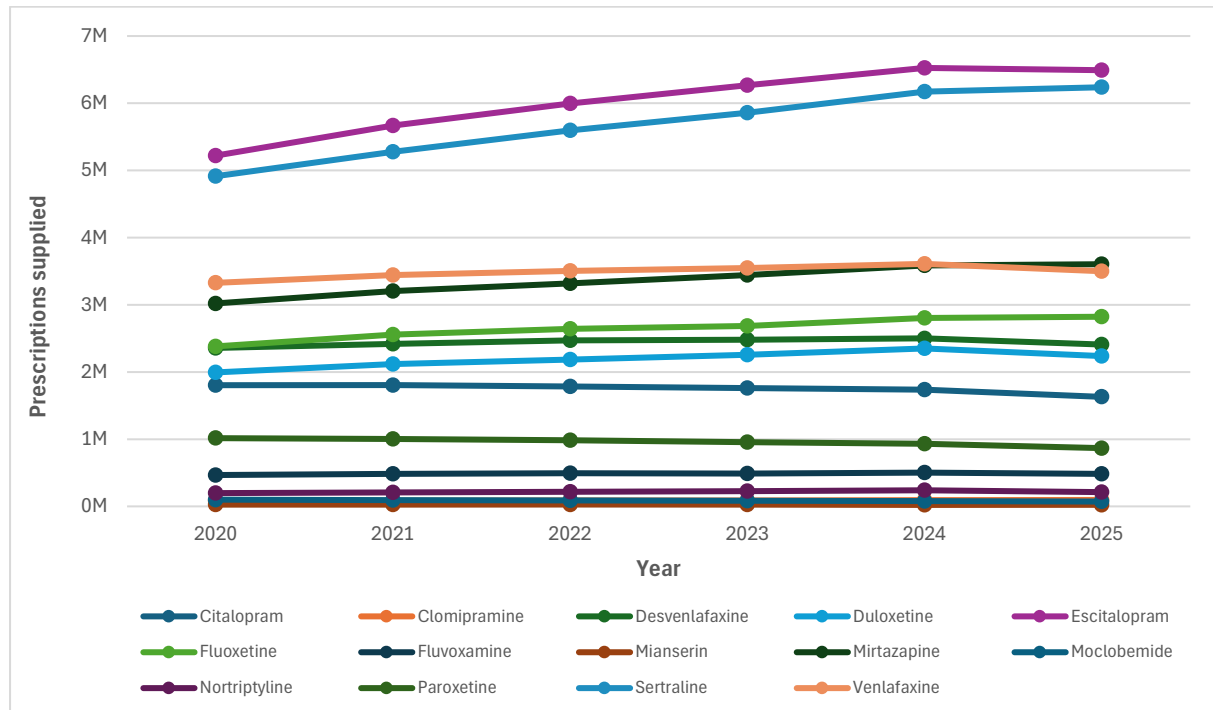


Source: R/PBS Section 85 Date of Supply Data.

Note: Patient counts are reported by medicine and may count patients more than once where they received more than one included antidepressant in a calendar year.

- 4.3 Total patients treated increased by approximately 30%, from 4.2 million in 2020 to 5.5 million in 2025. Across the 2020 to 2025 period, based on prevalent patient counts, patient utilisation was concentrated in escitalopram and sertraline, which together accounted for approximately 43% of patients. The four medicines with the greatest utilisation — escitalopram (22%), sertraline (21%), mirtazapine (12%) and venlafaxine (10%) — accounted for approximately 65% of patients.
- 4.4 Figure 2 shows annual prescriptions supplied for each included antidepressant between 2020 and 2025.

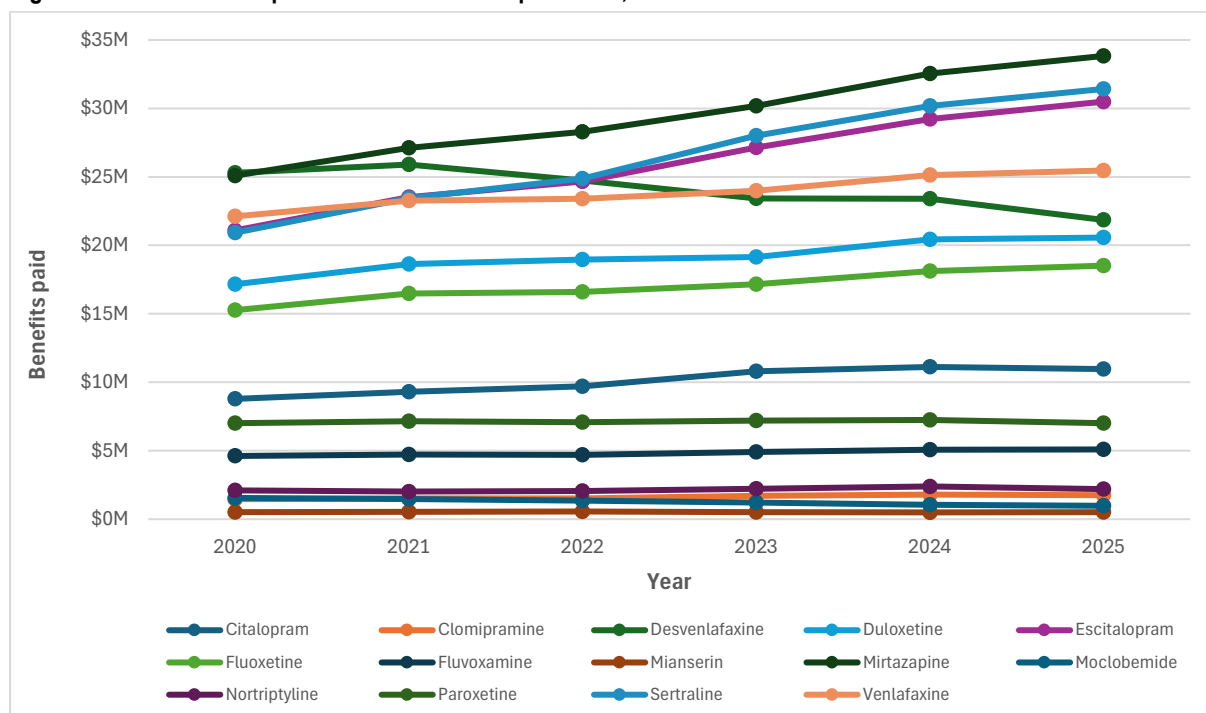
Figure 2: Prescriptions supplied for included antidepressants, 2020–2025



Source: R/PBS Section 85 Date of Supply Data.

- 4.5 Total prescriptions increased by approximately 16%, from 26.9 million in 2020 to 31.2 million in 2024, before decreasing slightly to 30.7 million in 2025. Across the 2020 to 2025 period, escitalopram and sertraline together accounted for approximately 40% of total prescriptions. The four medicines with the greatest utilisation — escitalopram (20%), sertraline (19%), venlafaxine (12%) and mirtazapine (11%) — accounted for approximately 63% of prescriptions. The reduction in 2025 should be interpreted in the context of the introduction of 60-day dispensing on 1 September 2024 for several medicines, which may reduce prescription volumes without a corresponding reduction in treated patients.
- 4.6 Figure 3 shows annual R/PBS benefits paid for each included antidepressant between 2020 and 2025.

Figure 3: R/PBS benefits paid for included antidepressants, 2020–2025



Source: R/PBS Section 85 Date of Supply Data.

- 4.7 Total R/PBS benefits paid increased by approximately 22%, from \$173.0 million in 2020 to \$210.6 million in 2025. Across the 2020 to 2025 period, expenditure was distributed across several medicines, with no single medicine accounting for more than 15% of total benefits paid. The five medicines with the greatest expenditure — mirtazapine (15%), sertraline (14%), escitalopram (13%), desvenlafaxine (12%) and venlafaxine (12%) — accounted for approximately 67% of total benefits paid.

### Private market utilisation

- 4.8 Private market utilisation for the included antidepressants was estimated as the difference between total market utilisation, based on IQVIA Australian Pharmacy Index (API) data, and PBS utilisation. As a complete 2025 calendar year was not available in the IQVIA API dataset, private market utilisation was calculated for the 2020 to 2024 period.
- 4.9 Across the included antidepressants, the estimated private market accounted for varying proportions of total utilisation over 2020 to 2024. Relatively larger private markets were observed for clomipramine (63%), fluoxetine (35%), nortriptyline (32%) and paroxetine (24%), while smaller private markets were observed for citalopram (7%), escitalopram (7%) and mirtazapine (2%). These differences may partly reflect variation in the breadth of current PBS restrictions, as well as broader clinical use for some medicines, consistent with the range of TGA-approved and Australian guideline indications summarised in Table 2. These medicine-level estimates informed the forecast private market utilisation used in the financial modelling.

## 5 Estimated financial impact to the R/PBS

- 5.1 Cost estimates were developed for the fourteen included antidepressants over the 2026 to 2031 forward estimates period to quantify the incremental increase in R/PBS expenditure that would be associated with the proposed PBS restriction changes. The estimates were developed using the general approach accepted by the PBAC for the listing of lamotrigine for bipolar disorder in November 2025, and assumed that 100% of forecast private market utilisation transitioned to R/PBS supply to reduce the risk of underestimating potential costs.

### ***Modelling approach and assumptions***

- 5.2 IQVIA API data were used to estimate total market utilisation for each included antidepressant. The API dataset contains sell-in data from pharmaceutical wholesalers and subscribing manufacturers to retail pharmacies and captures approximately 96% of wholesaler activity in Australia. As the API dataset reports units sold into pharmacies, R/PBS Section 85 Date of Supply prescription data were converted to units supplied to align with the total market utilisation data. Private market units for each medicine from 2020 to 2024 were then calculated by subtracting PBS units supplied from total market units.
- 5.3 Private market utilisation observed from 2020 to 2024 was projected at the medicine level over the 2026 to 2031 forward estimates period using linear extrapolation. For citalopram from 2028 to 2031, fluvoxamine from 2030 to 2031 and mirtazapine across the forward estimates period, this produced no positive forecast private market utilisation. As a result, no private market units were included in the financial estimates for those medicines in the relevant years.
- 5.4 Forecast medicine-level private market utilisation was then allocated to strengths and formulations based on the distribution of R/PBS utilisation observed over 2022 to 2024. Forecast private market units were incorporated into the Utilisation and Cost Model (UCM) workbooks, which converted units to prescriptions for the financial modelling. Table 4 summarises the key modelling inputs and assumptions.

**Table 4: Key inputs and assumptions used in the financial modelling**

| Input/assumption                                                    | Value                                                                                                                                            | Rationale/source                                                                                                                 |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Uptake of proposed PBS restriction changes                          | 100% of private market utilisation transitions to R/PBS supply                                                                                   | Assumed full transfer of private market utilisation to R/PBS supply to reduce the risk of underestimating potential R/PBS costs. |
| Distribution of utilisation between 30-day and 60-day prescriptions | 30-day/60-day split: 55%/45% in 2026; 42%/58% in 2027; 37%/63% in 2028–2031.                                                                     | Government impact analysis for 60-day dispensing arrangements. <sup>1</sup>                                                      |
| DPMQs applied in financial modelling                                | DPMQs were applied according to the relevant medicine, strength, formulation and dispensing quantity, including 30-day and 60-day prescriptions. | DPMQs were sourced from the PBS website as at 15 August 2026.                                                                    |
| PBS patient co-payments                                             | General \$25.00; concessional \$7.70                                                                                                             | PBS co-payment arrangements as at August 2026.                                                                                   |

<sup>1</sup> [https://oia.pmc.gov.au/sites/default/files/posts/2023/05/Impact%20Analysis\\_3.pdf](https://oia.pmc.gov.au/sites/default/files/posts/2023/05/Impact%20Analysis_3.pdf)

Abbreviations: DPMQ = Dispensed Price for Maximum Quantity; PBS = Pharmaceutical Benefits Scheme; R/PBS = Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme.

- 5.5 The modelling estimated the financial impact of shifting existing private market utilisation to PBS-subsidised supply and did not assume growth in the overall antidepressant market attributable to the proposed PBS restriction changes. This assumption was considered reasonable because the included antidepressants are already available as Restricted Benefits and many of the broader clinical uses may occur in patients with depression, anxiety or other conditions already captured by existing PBS indications. The generally low DPMQs for the included medicines also suggested that a substantial proportion of use outside current PBS restrictions may already be reflected in private market utilisation, supporting the use of observed private market utilisation as the basis for estimating incremental R/PBS uptake. The model also did not explicitly estimate switching or substitution between antidepressants; however, given the relatively similar acquisition costs associated with the included antidepressants, expenditure impacts arising from switching between included antidepressants were expected to be limited.

### Financial estimates

- 5.6 The estimated incremental net cost to the R/PBS resulting from the proposed PBS restriction changes is presented in Table 5, with estimates reported using the applicable cost ranges.

**Table 5: Estimated incremental net cost to the R/PBS resulting from the proposed PBS restriction changes**

| Medicine       | 2026           | 2027           | 2028           | 2029           | 2030           | 2031           | Total          |
|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| Citalopram     | ■ <sup>1</sup> | ■ <sup>1</sup> | \$0            | \$0            | \$0            | \$0            | ■ <sup>1</sup> |
| Clomipramine   | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| Desvenlafaxine | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>2</sup> |
| Duloxetine     | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>3</sup> |
| Escitalopram   | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| Fluoxetine     | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>3</sup> |
| Fluvoxamine    | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | \$0            | \$0            | ■ <sup>1</sup> |
| Mianserin      | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| Mirtazapine    | \$0            | \$0            | \$0            | \$0            | \$0            | \$0            | \$0            |
| Moclobemide    | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| Nortriptyline  | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| Paroxetine     | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| Sertraline     | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| Venlafaxine    | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> | ■ <sup>1</sup> |
| <b>Total</b>   | ■ <sup>2</sup> | ■ <sup>2</sup> | ■ <sup>2</sup> | ■ <sup>2</sup> | ■ <sup>2</sup> | ■ <sup>2</sup> | ■ <sup>4</sup> |

Note: Estimates were generated using medicine-specific UCM workbooks developed by the Department.

The redacted values correspond to the following ranges:

<sup>1</sup> > \$0 to < \$10 million

<sup>2</sup> \$10 to < \$20 million

<sup>3</sup> \$20 to < \$30 million

<sup>4</sup> \$90 to < \$100 million

- 5.7 The estimated incremental net cost to the R/PBS was relatively stable over the forward estimates, remaining within the \$10 million to < \$20 million range from 2026 to 2031, with a cumulative incremental cost of \$90 million to < \$100 million over the

2026 to 2031 period. Costs were concentrated among duloxetine (27% of the cumulative cost), fluoxetine (23%), desvenlafaxine (14%) and venlafaxine (10%), which together accounted for approximately 74% of the estimated cumulative cost. Across all medicines, the estimated financial impact was driven by forecast private market utilisation and patient contribution profiles. Consequently, medicines with relatively large private markets did not necessarily generate the largest estimated costs where patient contributions accounted for a substantial proportion of medicine costs.

- 5.8 For some medicines, extrapolation of historical private market utilisation resulted in no forecast private market utilisation in some or all years of the forward estimates period. In these instances, no incremental R/PBS expenditure was estimated for those years. This explained why some medicines had no estimated incremental R/PBS expenditure in particular years, and why mirtazapine had no estimated incremental cost across the full forward estimates period despite substantial existing PBS utilisation.

## **6 PBAC outcome**

- 6.1 The PBAC noted pre-PBAC responses from the RANZCP, the RACGP, NACCHO and one sponsor.
- 6.2 The PBAC recalled that, at its September 2023 meeting, it supported the Department considering, on a rolling basis, whether medicines that had transitioned to the F2 formulary may be suitable for review of their PBS restrictions. The PBAC also recalled that, at its September 2024 meeting, it supported the Department compiling further information to inform consideration of whether Unrestricted Benefit listings may be appropriate for several low-cost PBS-listed antidepressants.
- 6.3 The PBAC noted that the review included fourteen low-cost PBS-listed antidepressants on the F2 formulary that are currently listed as Restricted Benefits and have a DPMQ generally lower than the PBS general patient co-payment (\$25): citalopram, clomipramine, desvenlafaxine, duloxetine, escitalopram, fluoxetine, fluvoxamine, mianserin, mirtazapine, moclobemide, nortriptyline, paroxetine, sertraline and venlafaxine.
- 6.4 The PBAC noted that, for most of the included antidepressants, Australian clinical guidelines recommend use across a broader range of conditions than the current PBS indication(s), including mood, anxiety, obsessive-compulsive, pain-related and other conditions. The PBAC considered that indication-specific wording in the PBS restrictions may no longer reflect contemporary clinical practice.
- 6.5 For the 30-day solid oral dosage-form listings (tablets, capsules and orally disintegrating tablets), the PBAC recommended amending the current Restricted Benefit listings for the included antidepressants to Unrestricted Benefit listings, with the indication and any eligibility criteria removed.
- 6.6 For the 60-day solid oral dosage-form listings, the PBAC recommended retaining Restricted Benefit status; however, indication-specific wording should be removed and replaced with the existing clinical criterion that ‘the condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.’

- 6.7 For escitalopram oral liquid, which has a higher DPMQ than the escitalopram tablet formulations, the PBAC recommended retaining Restricted Benefit status for both the 30-day and 60-day listings and removing indication-specific wording. The PBAC also recommended adding a restriction concept for both listings requiring that the ‘Patient must be unable to swallow the solid dosage form of this drug,’ to maintain subsidised access for patients with a clinical need for the oral liquid while limiting use where a tablet formulation would be suitable.
- 6.8 The PBAC noted the Department’s modelling approach assumed that all forecast private market utilisation would transition to R/PBS supply following implementation of the proposed restriction changes. The PBAC considered this assumption reasonable and noted that it provided a conservative basis for estimating the financial impact of the proposed changes. The PBAC accepted the modelling approach and considered that the estimated incremental net cost to the R/PBS of \$90 million to < \$100 million over the 2026 to 2031 period was reasonable, noting that the proposed changes would broaden subsidised access across fourteen low-cost antidepressants in a therapeutic class associated with high utilisation.
- 6.9 The PBAC considered that the proposed changes would better align PBS-subsidised access for the included antidepressants with contemporary Australian clinical practice and noted that the changes were supported in the pre-PBAC responses received. The PBAC also noted that several of the included medicines had substantial estimated private market utilisation, suggesting that existing PBS restrictions may not fully reflect clinical need for subsidised access. The PBAC considered that broadening subsidised access may help reduce inequity for patients for whom out-of-pocket medicine costs are a barrier to treatment. This included concessional patients, patients who have reached the annual PBS Safety Net, and eligible First Nations people registered for the Closing the Gap PBS Co-payment Program, for whom PBS subsidy can materially reduce medicine costs.
- 6.10 The PBAC considered whether a price reduction should be sought in recognition of the additional utilisation expected to result from the proposed restriction changes. However, the committee noted the relatively low approved ex-manufacturer prices (AEMPs) of the affected medicines and that, as F2 medicines, they remain subject to applicable statutory price reduction and price disclosure arrangements. The PBAC also noted that, because these medicines have relatively low AEMPs, fixed dispensing-related fees and wholesale mark-ups comprise a substantial proportion of the R/PBS cost for prescriptions for these medicines, and therefore considered that a price reduction was not required.
- 6.11 The PBAC noted that cost-effectiveness had not been formally established for each of the broader clinical uses that may be subsidised following the proposed restriction changes. The committee considered it reasonable to assume that the included antidepressants were likely to represent acceptable value for money in the expanded population, noting that they are already PBS-listed medicines, had previously been accepted by the PBAC as cost-effective for their existing subsidised use, and have since reduced in price through statutory price reduction and price disclosure arrangements. The PBAC also noted that Australian clinical guidelines recommend use of many of the included antidepressants for conditions beyond their current PBS indications,

supporting the view that these medicines are clinically effective for those broader uses.

- 6.12 The PBAC recommended that the Department monitor utilisation of the included antidepressants following implementation of the restriction changes to assess whether utilisation remains broadly consistent with the estimates presented to the committee.

#### Outcome:

Recommended

## 7 Recommended listing

- 7.1 Amend the restriction type for each of the following **30-day** listings from Restricted Benefit to Unrestricted Benefit with the removal of all associated indications and criteria.

| MEDICINAL PRODUCT<br>medicinal product pack        | PBS item<br>code | Max. qty<br>packs | Max. qty<br>units | No. of<br>Rpts |
|----------------------------------------------------|------------------|-------------------|-------------------|----------------|
| citalopram 10 mg tablet, 28                        | 8702B            | 1                 | 28                | 5              |
| citalopram 20 mg tablet, 28                        | 8220P            | 1                 | 28                | 5              |
| citalopram 40 mg tablet, 28                        | 8703C            | 1                 | 28                | 5              |
| clomipramine hydrochloride 25 mg tablet, 50        | 1561E            | 1                 | 50                | 2              |
| desvenlafaxine 50 mg modified release tablet, 28   | 10234P           | 1                 | 28                | 5              |
| desvenlafaxine 50 mg modified release tablet, 28   | 10241B           | 1                 | 28                | 5              |
| desvenlafaxine 50 mg modified release tablet, 28   | 9366Y            | 1                 | 28                | 5              |
| desvenlafaxine 100 mg modified release tablet, 28  | 10231L           | 1                 | 28                | 5              |
| desvenlafaxine 100 mg modified release tablet, 28  | 10245F           | 1                 | 28                | 5              |
| desvenlafaxine 100 mg modified release tablet, 28  | 9367B            | 1                 | 28                | 5              |
| duloxetine 30 mg enteric capsule, 28               | 9155W            | 1                 | 28                | 0              |
| duloxetine 60 mg enteric capsule, 28               | 9156X            | 1                 | 28                | 5              |
| escitalopram 10 mg tablet, 28                      | 8700X            | 1                 | 28                | 5              |
| escitalopram 20 mg tablet, 28                      | 8701Y            | 1                 | 28                | 5              |
| fluoxetine 20 mg capsule, 28                       | 1434L            | 1                 | 28                | 5              |
| fluoxetine 20 mg tablet, 28                        | 8270G            | 1                 | 28                | 5              |
| fluvoxamine maleate 50 mg tablet, 30               | 8512B            | 1                 | 30                | 5              |
| fluvoxamine maleate 100 mg tablet, 30              | 8174F            | 1                 | 30                | 5              |
| mianserin hydrochloride 10 mg tablet, 50           | 1627P            | 1                 | 50                | 5              |
| mianserin hydrochloride 20 mg tablet, 50           | 1628Q            | 1                 | 50                | 5              |
| mirtazapine 15 mg tablet, 30                       | 9365X            | 1                 | 30                | 5              |
| mirtazapine 15 mg orally disintegrating tablet, 30 | 8855C            | 1                 | 30                | 5              |
| mirtazapine 30 mg tablet, 30                       | 8513C            | 1                 | 30                | 5              |
| mirtazapine 30 mg orally disintegrating tablet, 30 | 8856D            | 1                 | 30                | 5              |
| mirtazapine 45 mg tablet, 30                       | 8883M            | 1                 | 30                | 5              |
| mirtazapine 45 mg orally disintegrating tablet, 30 | 8857E            | 1                 | 30                | 5              |
| moclobemide 150 mg tablet, 60                      | 1900B            | 1                 | 60                | 5              |
| moclobemide 300 mg tablet, 60                      | 8003F            | 1                 | 60                | 5              |
| nortriptyline 10 mg tablet, 50                     | 2522R            | 1                 | 50                | 2              |
| nortriptyline 25 mg tablet, 50                     | 2523T            | 1                 | 50                | 2              |
| paroxetine 20 mg tablet, 30                        | 2242B            | 1                 | 30                | 5              |
| sertraline 50 mg tablet, 30                        | 2236Q            | 1                 | 30                | 5              |
| sertraline 100 mg tablet, 30                       | 2237R            | 1                 | 30                | 5              |
| venlafaxine 37.5 mg modified release capsule, 28   | 8868R            | 1                 | 28                | 0              |
| venlafaxine 75 mg modified release capsule, 28     | 8301X            | 1                 | 28                | 5              |
| venlafaxine 150 mg modified release capsule, 28    | 8302Y            | 1                 | 28                | 5              |

- 7.2 Remove the following item codes from the PBS schedule (with supply-only arrangement in place) so that each of the associated medicines are listed on a single Unrestricted Benefit item code:

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item<br>code | Max. qty<br>packs | Max. qty<br>units | No. of<br>Rpts |
|---------------------------------------------|------------------|-------------------|-------------------|----------------|
| escitalopram 10 mg tablet, 28               | 9432K            | 1                 | 28                | 5              |
| escitalopram 20 mg tablet, 28               | 9433L            | 1                 | 28                | 5              |
| sertraline 50 mg tablet, 30                 | 8836C            | 1                 | 30                | 5              |
| sertraline 100 mg tablet, 30                | 8837D            | 1                 | 30                | 5              |

- 7.3 Amend the following **60-day** listings as follows:

- removal of all the criteria and indications;
- adding the concept ID: 30501 for MDQ listings: *The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.*
- adding the administrative advice: (concept ID: 7607): *'No increase in the maximum number of repeats may be authorised'* to ensure treatment is limited to 6 months per prescription.

| MEDICINAL PRODUCT<br>medicinal product pack        | PBS item<br>code | Max. qty<br>packs | Max. qty<br>units | No. of<br>Rpts |
|----------------------------------------------------|------------------|-------------------|-------------------|----------------|
| citalopram 10 mg tablet, 28                        | 14313H           | 2                 | 56                | 2              |
| citalopram 20 mg tablet, 28                        | 14490P           | 2                 | 56                | 2              |
| citalopram 40 mg tablet, 28                        | 14518D           | 2                 | 56                | 2              |
| desvenlafaxine 100 mg modified release tablet, 28  | 14384C           | 2                 | 56                | 2              |
| desvenlafaxine 100 mg modified release tablet, 28  | 14489N           | 2                 | 56                | 2              |
| desvenlafaxine 100 mg modified release tablet, 28  | 14545M           | 2                 | 56                | 2              |
| desvenlafaxine 50 mg modified release tablet, 28   | 14383B           | 2                 | 56                | 2              |
| desvenlafaxine 50 mg modified release tablet, 28   | 14418W           | 2                 | 56                | 2              |
| desvenlafaxine 50 mg modified release tablet, 28   | 14451N           | 2                 | 56                | 2              |
| duloxetine 60 mg enteric capsule, 28               | 14712H           | 2                 | 56                | 2              |
| escitalopram 10 mg tablet, 28                      | 14349F           | 2                 | 56                | 2              |
| escitalopram 20 mg tablet, 28                      | 14415Q           | 2                 | 56                | 2              |
| fluoxetine 20 mg capsule, 28                       | 14548Q           | 2                 | 56                | 2              |
| fluoxetine 20 mg tablet, 28                        | 14717N           | 2                 | 56                | 2              |
| fluvoxamine maleate 100 mg tablet, 30              | 14314J           | 2                 | 60                | 2              |
| fluvoxamine maleate 50 mg tablet, 30               | 14488M           | 2                 | 60                | 2              |
| mianserin hydrochloride 10 mg tablet, 50           | 14366D           | 2                 | 100               | 2              |
| mianserin hydrochloride 20 mg tablet, 50           | 14505K           | 2                 | 100               | 2              |
| mirtazapine 15 mg orally disintegrating tablet, 30 | 14369G           | 2                 | 60                | 2              |
| mirtazapine 15 mg tablet, 30                       | 14507M           | 2                 | 60                | 2              |
| mirtazapine 30 mg orally disintegrating tablet, 30 | 14370H           | 2                 | 60                | 2              |
| mirtazapine 30 mg tablet, 30                       | 14473R           | 2                 | 60                | 2              |
| mirtazapine 45 mg orally disintegrating tablet, 30 | 14475W           | 2                 | 60                | 2              |
| mirtazapine 45 mg tablet, 30                       | 14561J           | 2                 | 60                | 2              |
| moclobemide 150 mg tablet, 60                      | 14560H           | 2                 | 120               | 2              |
| moclobemide 300 mg tablet, 60                      | 14442D           | 2                 | 120               | 2              |
| paroxetine 20 mg tablet, 30                        | 14367E           | 2                 | 60                | 2              |
| sertraline 100 mg tablet, 30                       | 14506L           | 2                 | 60                | 2              |
| sertraline 50 mg tablet, 30                        | 14400X           | 2                 | 60                | 2              |
| venlafaxine 150 mg modified release capsule, 28    | 14402B           | 2                 | 56                | 2              |
| venlafaxine 75 mg modified release capsule, 28     | 14472Q           | 2                 | 56                | 2              |

- 7.4 Remove the following item codes from the PBS schedule (with supply-only arrangement in place) so that each of the associated medicines are listed on a single (60-day) Restricted Benefit item code:

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item<br>code | Max. qty<br>packs | Max. qty<br>units | No. of<br>Rpts |
|---------------------------------------------|------------------|-------------------|-------------------|----------------|
| escitalopram 10 mg tablet, 28               | 14519E           | 2                 | 56                | 2              |
| escitalopram 20 mg tablet, 28               | 14416R           | 2                 | 56                | 2              |
| sertraline 50 mg tablet, 30                 | 14403C           | 2                 | 60                | 2              |
| sertraline 100 mg tablet, 30                | 14404D           | 2                 | 60                | 2              |

- 7.5 Amend the restriction of escitalopram 20 mg/mL oral liquid, as follows:
- removal of associated indications and criteria;
  - restricting its use in patients who cannot swallow the solid dosage form by adding the new concept: *Patient must be unable to swallow the solid dosage form of this drug;*
  - retaining the concept ID: 30502 in the 60-day listing (14546N): *The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.*

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item<br>code | Max. qty<br>packs | Max. qty<br>units | No. of<br>Rpts |
|---------------------------------------------|------------------|-------------------|-------------------|----------------|
| escitalopram 20 mg/mL oral liquid, 15 mL    | 10181W           | 1                 | 1                 | 5              |
| escitalopram 20 mg/mL oral liquid, 15 mL    | 14546N           | 2                 | 2                 | 2              |

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

## 8 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.