Access to MDMA and psilocybine under the Authorised Prescriber and Special Access Schemes

Data current to 18 August 2026

The information below has been extracted from the Therapeutic Goods Administration's internal reporting relating to Authorised Prescriber approvals, Authorised Prescriber six-monthly reports, sponsor reporting and Special Access Scheme notifications and applications for MDMA and psilocybine. Information reflects records held by the TGA as at 18 August 2026. Where reporting datasets rely on statutory reporting by Authorised Prescribers or sponsors, figures are limited to information received and recorded by the TGA as at that date.

Authorised Prescriber patients

Table 1: Patients treated under the Authorised Prescriber scheme

Reporting period	Product	Total patients treated	Patients newly commenced
Jul-Dec 2023	MDMA	**1**	**1**
Jul-Dec 2023	Psilocybine	**0**	**0**
Jan-Jun 2024	MDMA	**19**	**18**
Jan-Jun 2024	Psilocybine	**7**	**7**
Jul-Dec 2024	MDMA	**44**	**34**
Jul-Dec 2024	Psilocybine	**25**	**23**
Jan-Jun 2025	MDMA	**43**	**34**
Jan-Jun 2025	Psilocybine	**31**	**17**
Jul-Dec 2025	MDMA	**95**	**77**
Jul-Dec 2025	Psilocybine	**31**	**27**
Jan-Jun 2026	MDMA	**104**	**92**
Jan-Jun 2026	Psilocybine	**47**	**38**

Methodology and caveats

The figures were obtained from six-monthly reports submitted by Authorised Prescribers under regulation 47B of the *Therapeutic Goods Regulations 1990*.

Authorised Prescribers are required to submit reports to the TGA every six months for each authorisation they hold and declare:

- the number of patients newly commenced on treatment during the reporting period, and
- the total number of patients treated during the reporting period.

A prescriber of psychedelic medicinal products may hold an Authorised Prescriber approval for either MDMA or psilocybine, or separate approvals for both products.

The information provided in six-monthly reports is self-reported by Authorised Prescribers. No patient-level information is provided in these reports and potential duplicate reporting cannot be identified or removed.

The TGA does not hold prescription data. A patient may receive multiple administrations or doses of psychedelic medicinal products as clinically appropriate.

The number of patients treated in a reporting period may not equal the number of patients treated in previous reporting periods plus the number of patients newly commenced on treatment. Patients may discontinue treatment, complete treatment, or otherwise stop being reported between reporting periods.

Reporting periods run from 1 January to 30 June and 1 July to 31 December each year.

The figures for the reporting period 1 January 2026 to 30 June 2026 reflect reports received and recorded by the TGA as at 18 August 2026. Additional reports for that reporting period may be received after this date.

Authorised Prescriber Approvals

Table 2: Authorised Prescribers approvals granted

Period: 1 July 2023 to 18 August 2026

Reporting period	MDMA	Psilocybine
Jul-Dec 2023	**3**	**3**
Jan-Jun 2024	**2**	**2**
Jul-Dec 2024	**7**	**8**
Jan-Jun 2025	**9**	**5**
Jul-Dec 2025	**28**	**22**
Jan-Jun 2026	**20**	**24**
1 Jul 2026 to 18 Aug 2026	**2**	**5**

Table 3: Current active Authorised Prescribers

As at 18 August 2026

Product	Number of active Authorised Prescribers
MDMA	**61**
Psilocybine	**61**

Methodology and caveats

The figures were obtained from the TGA's internal reporting for Authorised Prescriber approvals relating to MDMA and psilocybine.

Approval figures represent Authorised Prescriber approvals granted during the relevant period.

The figures include approvals current and historical as recorded in the TGA's internal systems as at 18 August 2026.

The active Authorised Prescriber figures reflect approvals current as at 18 August 2026.

Historical counts of active Authorised Prescribers are not routinely reported by the TGA and have therefore not been included.

A prescriber may hold approvals for both MDMA and psilocybine and may therefore be included in both product categories.

Sponsor reported supply information

Sponsor reporting records relating to MDMA and psilocybine products supplied under Authorised Prescriber scheme for the reporting periods from 1 July 2023 to 30 June 2026.

Table 4: Sponsor-reported supply information

Reporting period	Product	Dosage form	Pack size	Quantity supplied through AP pathway
Jan-Jun 2026	MDMA 40 mg	Capsules	25 capsules	38
Jan-Jun 2026	MDMA 100%	Powder (for compounding)	1 g vial	1
Jan-Jun 2026	Psilocybine 100%	Powder (for compounding)	10 g vial	1

Methodology and caveats

The figures were obtained from sponsor reports submitted to the TGA relating to the supply of MDMA and psilocybine products supplied under the Authorised Prescriber pathway.

Sponsors are required to submit reports to the TGA every six months. Reporting periods run from 1 January to 30 June and 1 July to 31 December each year.

Sponsor reporting records were reviewed for the reporting periods from 1 July 2023 to 30 June 2026.

The information provided in sponsor reports is self-reported by sponsors and reflects information held by the TGA as at 18 August 2026.

The TGA identified one sponsor report containing information relevant to this request for the reporting period 1 January 2026 to 30 June 2026.

The figures reflect reports received and recorded by the TGA as at 18 August 2026. Additional reports for previous reporting periods may be received after this date.

No sponsor reports relating to MDMA or psilocybine products were identified for earlier reporting periods.

Accordingly, the figures should not be interpreted as representing total supply volumes or all sponsors supplying MDMA or psilocybine products under the Authorised Prescriber scheme between 1 July 2023 and 18 August 2026.

Commercially sensitive information identifying individual sponsors has not been included.

Special Access Scheme

The TGA has not identified any SAS A notifications or SAS B approvals relating to MDMA or psilocybine during the period 1 July 2023 to 18 August 2026.

Methodology and Caveats

The TGA's internal reporting was searched for Special Access Scheme notifications and applications relating to MDMA and psilocybine.

Records were reviewed for the period 1 July 2023 to 18 August 2026.

No SAS Category A notifications or SAS Category B approvals relating to MDMA or psilocybine were identified during the relevant period.

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

FOI 27-3566

Branch/Section: AEMDS/PBFT

Scope of the request:

Item 5: I am seeking information similar to what was released under FOI 26-2560, updated for the period beginning 1 January 2026. FOI 26-2560 covered July 2023 through December 2025, so I am not seeking the existing briefing document itself. ***Note: Limited to adverse event reporting information for the requested period commencing January 2026, and for reports received to date…'***

- Document that contains the total number of adverse events reported to the TGA associated with the prescription of 3,4,-Methylenedioxymethamphetamine (MDMA) under the Authorised Prescriber scheme since 1 January 2026.
- Document that contains the total number of adverse events reported to the TGA associated with the prescription of psilocybin under the Authorised Prescriber scheme since 1 January 2026. The timeframe for this request is from 1 January 2026 to 2 September 2026.
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Name of the Medicine	**Total number of adverse events reported to TGA**
3,4 - Methylenedioxymethamphetamine (MDMA)	2
Psilocybin	0

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