Guidance for Authorised Prescribers of MDMA and psilocybin

July 2026

Purpose

To provide guidance to psychiatrists following the Therapeutic Goods Administration's (TGA) May 2026 recommendations regarding access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybin for the purpose of psychedelic-assisted therapy (PAT).

Background

RANZCP is committed to supporting those living with a mental health condition with safe and evidence-based care. This is crucial for emerging treatment modalities such as PAT, which call for cautious regulation to prevent unacceptable risks of public harm. RANZCP has developed a range of clinical and community resources to this end, including the Psychedelic training framework for psychiatrists and clinical memoranda on the Therapeutic use of psychedelic substances and Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression (for other resources and future releases, please refer to the RANZCP's Psychedelics hub).

From 1 July 2023, amendments to the Poisons Standard implemented by the TGA have permitted the use of MDMA in the treatment of post-traumatic stress disorder and the use of psilocybin for treatment resistant depression. These agents may only be accessed by registered psychiatrists approved via the TGA's Authorised Prescriber scheme.

In 2025 and 2026, the TGA conducted a consultation on their *Review of the Authorised Prescriber scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybin for use with psychotherapy in mental health conditions* outlining a series of recommendations (the Review). RANZCP supports ongoing regulatory adjustments that bolster the safety and effectiveness of mental health care.

The below guidance has been prepared to outline RANZCP's guardrails and expectations of Authorised Prescribers (AP) during this period of regulatory transition.

Recommendations

Recommendation 1 – Psychiatrist experience

> *"The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have complied with RANZCP's 'Psychedelic training framework for psychiatrists.'"*

Regarding appropriate supervision arrangements and peer review, RANZCP recommends the following:

1. APs without prior experience in PAT clinical trials should be supervised for at least the first five patients for a given type of PAT by an Australian-registered psychiatrist with demonstrated experience in that specific PAT modality.

   This supervision should:

   (a) Occur to a minimum of 10 hours of structured one-on-one supervision with the designated psychiatrist. This threshold should be independently met for each PAT modality for which the AP intends to prescribe (i.e., MDMA, psilocybin).

   (b) Be specifically focussed on PAT.

(c) Address issues of clinical decision-making, risk-management, protocol adherence, and integration practices.

(d) Occur independently of PAT formal training programs, workshops, or peer review groups.

2. It is further recommended that all APs:

   (a) Engage in regular and ongoing peer review activities specific to PAT. A target of ten hours per year is recommended.

   (b) Participate in a multidisciplinary team setting in which PAT cases and clinical approaches are actively discussed. A target of one hour per week is recommended.

Recommendation 2 – Therapy 'dyad' qualifications

> *"The PAT dyad must include at least ONE therapist registered with a National Board that provides regulatory oversight of psychotherapy, specifically, the Psychology, Medical, Nursing and Midwifery and Occupational Therapy Boards. The Authorised Prescriber is responsible for determining the qualifications and experience of any ADDITIONAL therapists involved in sessions."*

RANZCP views professional registration as means to promote accountability for poor practices, however, risks to the public must be reduced in the first instance with appropriate training and skills. The composition of the therapeutic dyad must reflect and be responsive to the unique risks of PAT.

RANZCP recommends the following minimum conditions:

1. The therapeutic dyad should include at least one medical practitioner.
2. All practitioners involved with PAT must be registered with Ahpra or their equivalent governing body, as well as having current appropriate clinical indemnity insurance.
3. The AP retains responsibility for ensuring all dyad members are competent to participate in the therapeutic dyad. To this end, the AP should document their explicit endorsement of each dyad member prior to their participation.
4. The AP should participate in the therapeutic dyad:

   (a) For at least the first four patients for whom they prescribe the psychedelic drug

   (b) Thereafter, at least two patients for whom they prescribe the drug per calendar year.

5. Dyad members that do not have demonstrated skills and experience in PAT delivery must meet the following conditions:

   (a) APs without prior PAT clinical trial experience should adhere to a supervisory arrangement as proposed by the RANZCP for Recommendation 1.

   (b) Non-APs should undergo direct in-session supervision and post-session case debriefing with the AP. This arrangement should occur for no less than four sessions and continue if necessary at the AP's discretion. The duration of this supervisory arrangement should be guided by the AP's assessment of the therapist's practices, competencies, and skills specific to PAT.

Recommendation 3 – Level of AP oversight

> *"The AP psychiatrist is responsible for conducting patient screening and ongoing informed consent face to face (online or in-person).*

The AP must be present in-person during the administration of the psychedelic (this does not need to be the full dosing day). This ensures the AP can manage immediate issues and severe adverse events that may occur."

RANZCP agrees that patient screening and ongoing informed consent must be conducted by the AP and occur face-to-face, either in-person or by video. It is further agreed that the AP must also be physically present during the administration of the psychedelic dose. Thereafter, it is essential that the AP psychiatrist is either physically present for the rest of the dosing day or has delegated an appropriate medically trained doctor to be available for prompt care at all times the AP is absent.

Recommendation 4 – Appropriate site location

"Prescribers must provide details of the treatment site to demonstrate it is a suitable medically supervised environment. The AP is responsible for ensuring the site meets the following requirements:

a. *Equipment and trained staff for clinical care, monitoring, medical/behavioural emergencies and emergency resuscitation.*
b. *Secure storage and record keeping for Schedule 8 medicines as per jurisdictional regulations.*
c. *Ability to address treatment-emergent adverse events, with immediate access to rescue medications.*
d. *Located near (within 15 minutes of) an accredited healthcare facility with an emergency department.*
e. *Clear documentation of treatment plans, consent, and adverse events.*
f. *Adheres to all state/territory requirements."*

It is RANZCP's preference that PAT occur in day hospitals and inpatient settings for their preparedness to manage patient safety and monitory needs. Beyond these settings, PAT should occur in accredited healthcare facilities located near an emergency department. It is RANZCP's position that the suitability of any PAT site against these requirements is best determined through independent scrutiny and ongoing accreditation.

Additional resources

The following resources elaborate on therapist requirements and therapy methodology and technique in PAT.

- Clinical Practice Guideline for the Appropriate Use of Methylenedioxymethamphetamine (MDMA)-assisted Psychotherapy for Post-traumatic Stress Disorder by Yong et al. (2026)
- A Manual for MDMA-Assisted Psychotherapy in the Treatment of PTSD by Michael Mithoefer et al (2015)
- The Yale Manual for psilocybin-assisted therapy for depression by Guss et al. (2019)
- Developing Guidelines and Competencies for the training of Psychedelic Therapists by Janis Phelps. Journal of Humanistic Psychology 1-38 2017

Disclaimer

This information is intended to provide general guidance to practitioners, and should not be relied on as a substitute for proper assessment with respect to the merits of each case and the needs of the patient. The RANZCP endeavours to ensure that information is accurate and current at the time of preparation, but takes no responsibility for matters arising from changed circumstances, information or material that may have become subsequently available.

REVISION RECORD

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