

14 May 2026

Prof Robyn Langham AM
Chief Medical Advisor
Therapeutic Goods Administration

By email: [REDACTED]

Dear Prof Langham

Re: RANZCP Response to the TGA's Proposed Final Recommendations – Authorised Prescriber Scheme for MDMA and Psilocybin

I write on behalf of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) to formally respond to the TGA's proposed final recommendations regarding the Authorised Prescriber (AP) application process for psychedelic-assisted therapy (PAT). The RANZCP acknowledges the TGA's efforts in undertaking this review and values the constructive dialogue between our organisations.

Having carefully considered the TGA's proposed recommendations, the RANZCP is unable to support any changes that would represent a relaxation of the standards currently applicable to the AP scheme. The RANZCP is not aware of sufficient evidence to justify such a change at this time and respectfully urges the TGA to maintain existing requirements until more robust, longitudinal evidence is available.

The RANZCP's position, as set out in its Clinical Memoranda and *Psychedelic Training Framework for Psychiatrists*, remains unchanged. The RANZCP takes this opportunity to formally reiterate the following:

- The current evidence base for the therapeutic use of MDMA and psilocybin remains **limited and still emerging**. The RANZCP maintains that PAT should be regarded as a treatment of last resort, indicated only for post-traumatic stress disorder (in the case of MDMA) and treatment-resistant depression (in the case of psilocybin), and only where other established treatment modalities have been exhausted.
- **Psychiatrist oversight is essential and non-negotiable.** Treatment protocols must be led by appropriately trained psychiatrists with specific experience in PAT. The prescribing psychiatrist bears overall clinical and ethical responsibility for patient selection, therapist selection, appointment and supervision, comprehensive assessment, informed consent, ongoing monitoring of outcomes, and follow-up care.
- **Psychotherapy constitutes an integral and indispensable component of PAT.** The integration of structured psychotherapeutic support with the clinical administration of MDMA or psilocybin must be regarded as fundamental to treatment,

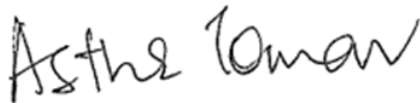
consistent with the current evidence base and best practice standards.

- **All members of the therapeutic dyad must hold registration with an appropriate National Board** that provides professional and regulatory oversight. The RANZCP notes that the dyad must include at least one medical practitioner. The RANZCP does not support any expansion of the therapeutic dyad to include practitioners who fall outside such oversight frameworks, as this would present an unacceptable and unjustifiable risk to patient safety and welfare.
- **The systematic and longitudinal collection of clinical data is imperative**, encompassing the comprehensive reporting of adverse events. The RANZCP strongly advocates for the establishment of independently administered clinical quality registries, funded through appropriate government mechanisms, as an urgent priority to inform future evidence-based regulatory decision-making.
- The RANZCP notes with considerable concern the **documented emergence of serious adverse events** in connection with PAT and reiterates its position that the current AP scheme must be administered with the utmost rigour and with stringent safeguards firmly in place.

Notwithstanding these reservations, the RANZCP welcomes the opportunity for further dialogue and would be pleased to meet with the TGA to discuss these matters in greater depth.

To arrange a meeting, please contact Dr Kenley Kuoch (Manager, Practice & Standards) at policy@ranzcp.org.

Yours sincerely



Dr Astha Tomar
RANZCP President

Ref 8142