

## Purpose

To provide a training framework to assist psychiatrists applying to become authorised prescribers of MDMA and psilocybin to identify a suitable course.

## Background

In Australia from 1 July 2023, the Therapeutic Goods Administration (TGA) amended the Poisons Standard to add MDMA and psilocybin, permitting their use as controlled drugs only in post-traumatic stress disorder (PTSD) and treatment resistant depression (TRD), respectively.

Any psychiatrist who wants to prescribe MDMA or psilocybin under the TGA Authorised Prescriber Scheme must have a good knowledge and understanding not only of the medicines, but also of the psychotherapeutic processes involved in psychedelic-assisted therapy (PAT).

Comprehensive training in PAT is essential before prescribing, administering and managing the use of MDMA or psilocybin and the accompanying therapy.

RANZCP has not currently developed or endorsed any particular training program, but has developed this to assist psychiatrists in ensuring they have undertaken appropriate and formal training, by self-assessing a training course against the criteria outlined.

## Checklist for training courses

It is suggested that any training course be comprised of three core components: (1) theoretical and didactic knowledge; (2) hands-on training; (3) observation, supervised practice and assessment of skills. This covers three general topics: *knowledge*; *safety and ethics*; and *hands-on training*. Each area is further subdivided into competencies, each covering a specific aspect.

It is noted that this list is the minimum requirements for a training course and psychiatrists are able to further their knowledge outside these competencies and skills.

## Course overview

In addition to the below table below covering competencies and skills, training courses should demonstrate:

- the qualifications of the providers, including having appropriate educational background (industry-independent) and ability to provide training for use of MDMA for PTSD and psilocybin for TRD in an Australian clinical context.
- interpretation of relevant research data by psychiatrists with appropriate academic and clinical skills including limitations of current data and interpretations of data and emerging information.
- a clear methodology, learning objectives, and structure of the training. While a component of the training may be delivered online, there should be a significant experiential part of the training that is delivered in-person.
- how the providers will evaluate the competency of the participants (exit written/practical tests and certification desirable).

- evaluation of the quality of the training.

## Competencies and skills

Competency	Skills
<b>Knowledge</b>	1. Basic mechanisms of psychedelics action including: <ul style="list-style-type: none"> <li>• Medications</li> <li>• Psychotherapy</li> <li>• Details focused on MDMA for PTSD and psilocybin for treatment resistant depression</li> </ul>
	2. Neurological principles of psychedelic brain activity: <ul style="list-style-type: none"> <li>• Effects of concurrent medications.</li> </ul>
	3. General risks and benefits of psychedelic therapy
	4. Knowledge of evidence base for the range of parameters for use <ul style="list-style-type: none"> <li>• Understanding of the below for individual patients, including:               <ol style="list-style-type: none"> <li>Eligibility of patients and that suitability will vary</li> <li>Limited nature of evidence for suitable dosages and treatment protocols</li> <li>Psychotherapy options and unknowns about which may be most suitable</li> <li>Potential adverse effects</li> <li>PAT provision in the context of holistic care</li> <li>Importance of keeping records including outcome measures.</li> </ol> </li> </ul>
	5. Regulatory and professional standards landscape: <ul style="list-style-type: none"> <li>• RANZCP guidelines</li> <li>• TGA approval</li> <li>• Local legislative and governance requirements</li> <li>• Cultural safety</li> <li>• Privacy</li> </ul>
	6. Evidence base on efficacy and safety of MDMA for PTSD and psilocybin for treatment resistant depression.
<b>Safety and ethics</b>	7. Screening and risk stratification: <ul style="list-style-type: none"> <li>• Advanced knowledge of indications and contraindications</li> <li>• Clinical care of patients receiving PAT, including:               <ol style="list-style-type: none"> <li>Pre-treatment work-up and assessment</li> <li>Obtaining informed consent including pre-treatment discussion of physical touch in sessions</li> <li>Need for adjustment of the patients' medication regime or augmenting therapies.</li> <li>Monitoring therapeutic response including use of rating scales and quality of life measures.</li> <li>Monitoring and managing side effects</li> <li>Making a decision about when and how to cease treatment</li> </ol> </li> </ul>

	vii. Post course assessment and ongoing care
	8. Diagnosis and management of medical emergencies
	9. Setting of care (e.g. clinical environment)
	10. Recognising and addressing needs of special populations: <ul style="list-style-type: none"> <li>• Pregnant women</li> <li>• Older people</li> </ul>
	11. Recognising and addressing disease-specific conditions and complications, and exclusions e.g.: <ul style="list-style-type: none"> <li>• Psychosis</li> <li>• Mania</li> <li>• Drug/alcohol</li> <li>• Physical health conditions</li> </ul>
<b>Hands-on training</b>	12. Supervision and instruction in the selection, treatment, management and follow up, of an actual psychiatric patient treated with PAT
	13. Participation in psychotherapy provision as part of treating dyad
	14. Completion of RANZCP Framework for recording safety and quality when using MDMA and psilocybin as part of Psychedelic-Assisted Therapy (PAT)

### Ongoing training and Continuing Professional Development

All psychiatrists delivering PAT should continually maintain and improve their skills in a collaborative manner with colleagues. Ongoing CPD should include membership of a psychiatric peer review group with a specific interest in PAT that meets regularly for discussion, education and support.

### Resources

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

- A Manual for MDMA-Assisted Psychotherapy in the Treatment of PTSD by Michael Mithoefer et al.
- The Yale Manual for psilocybin-assisted therapy for depression
- Developing Guidelines and Competencies for the training of Psychedelic Therapists by Janis Phelps. Journal of Humanistic Psychology 1-38 2017