



Therapeutic Goods Administration (TGA) Consultation Review

Accessing MDMA and Psilocybin Under the Authorised Prescriber (AP) Scheme

Expanding Clinical Recognition: A Policy Submission from the Australian Multidisciplinary
Association for Psychedelic Practitioners (AMAPP)

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7th August 2025

Executive Summary

Overview

This response submission addresses Questions 1–8 of the TGA’s Targeted Consultation Paper. It outlines our position alongside a clinical and policy analysis, draws on international research and Australian practice, presents AMAPP’s training and credentialing standards, and offers recommendations for regulatory reform.

In summary, the current AP scheme functionally restricts psychedelic-assisted psychotherapy facilitation to psychiatrists and clinical psychologists. The implied exclusion of psychotherapists, counsellors, social workers, and other qualified professionals undermines the therapeutic integrity of psychedelic-assisted psychotherapy and equitable access to care. Psychedelic-assisted psychotherapy requires specific therapeutic expertise—including relational, somatic, and trauma-informed modalities—commonly held by psychotherapists and counsellors. Many of Australia’s foremost clinicians, educators, and researchers in this field are psychotherapists, yet they are effectively excluded. This exclusion is clinically indefensible, inconsistent with international best practice, and worsens workforce shortages in rural and remote areas, where access to psychiatrists and clinical psychologists is already limited.

AMAPP’s Recommendations

1. Consider expanding the Authorised Prescriber scheme to include:

- Non-psychiatrist medical doctors, palliative care physicians and addiction physicians who have established mental health experience, complete accredited PAP training, and meet AMAPP credentialing standards.
- Multidisciplinary team models where prescribing doctors work alongside fully credentialed multidisciplinary psychedelic therapists, ensuring safe and holistic care delivery.
- Future inclusion of Paramedic Practitioners and Clinical Nurse Specialists, once frameworks and credentialing processes are finalised, to support emergency preparedness and access equity.

2. Competency-Based Credentialing and Supervision Framework

- Shift from “profession = qualification” to “demonstrated PAP competency”.
- Define clear didactic, experiential, supervision, and ethical training requirements for safe psychedelic-assisted psychotherapy (PAP) delivery.
- Implement a credentialing model recognising practitioners beyond psychiatry and clinical psychology, including clinical psychotherapists, clinical counsellors, mental health social workers, mental health nurses, specialist GPs with psychiatry training, and paramedics.
- Broaden workforce capacity to ensure equitable access, especially in rural and remote areas where specialist availability is limited.

3. Multidisciplinary Team Approach

- Broaden the Authorised Prescriber pathway to consider a broad range of non-psychiatrist medical practitioners—including GPs, addiction medicine specialists, pain and palliative care physicians, and emergency doctors—who already provide frontline mental health support and counselling.
- Broaden workforce eligibility to allow appropriately trained multidisciplinary teams.
- Maintain high safety standards while reducing duplication of clinical oversight, improving efficiency and accessibility.
- Enable regional, rural, and remote practitioners to safely deliver PAP under clear protocols, improving access for geographically isolated communities.
- See Appendix D: Psychedelic Clinical Trial Therapist Configurations

4. Flexible Treatment Settings

- Allow PAP delivery beyond day hospitals and inpatient units where stringent safety, governance, and emergency-response criteria are met.
- Support delivery in community-based and regional settings, ensuring patients in rural and remote areas can access care without prohibitive travel.
- Ensure robust oversight via pre-prescribed rescue medications and competent on-site teams trained in emergency response.
- Sites must have robust ethical frameworks, clear boundaries, and structured incident reporting and escalation pathways.

5. Cost and Access Improvements

- Reduce unnecessary infrastructure and supervisory layers that drive up treatment costs, restricting access for eligible, treatment-resistant individuals.
- Support health economics by saving costs for government, third-party payers, patients, and the broader healthcare system, improving affordability in underserved rural and remote areas.

6. Inclusive Access and Public Health Impact

- Enable Australia's most vulnerable mental-health cohorts to access high-quality, novel treatments when conventional therapies have failed.
- Promote access through clinical, community-based, and culturally appropriate settings, ensuring equity and cultural safety for First Nations peoples, rural and remote residents, and culturally diverse communities.

Concluding Statement

The current TGA requirement that a clinical psychologist or psychiatrist must be present in all PAP sessions is not evidence-based and is inconsistent with international protocols. Several other accredited professions are registered with national professional registration bodies that provide oversight of educational and practice requirements, codes of ethics, supervision requirements, and continuing professional development. These include registered psychotherapists, mental health nurses, mental health social workers, specialist GPs, paramedics, palliative care and addiction physicians. Clinical psychologists do not inherently provide superior safety; safety is already ensured through the presence and oversight of an authorised psychiatrist. This restriction exacerbates inequity in rural and remote communities, where access to these specialists is limited or absent. **Indeed, most Australian clinical trials, following established international research protocols, do not require that a psychiatrist or clinical psychologist be present in the therapy room; instead, they routinely and extensively utilise multidisciplinary teams, demonstrating safe and effective practice without compromising patient outcomes.** These reforms will enable safe, equitable, and cost-effective access to psychedelic-assisted psychotherapy, improving patient care, protecting public health, and ensuring access for all Australians, including rural and remote communities, while aligning Australia with global best practice.

1. Introduction

1.1 About AMAPP

The Australian Multidisciplinary Association for Psychedelic Practitioners (AMAPP) is a national peak body representing professionals involved in the clinical, cultural, and ethical delivery of psychedelic-assisted psychotherapy. Our membership spans psychotherapists, psychiatrists, psychologists, general practitioners, integrative doctors, nurses, paramedics, physicians, social workers, and other relevant health professionals. AMAPP includes clinicians involved in Australian and international clinical trials, curriculum developers, integration therapists, and supervisors. AMAPP is united by a commitment to the safe and effective application of Psychedelic-Assisted Therapy (PAP).

1.2 TGA Acknowledgement

AMAPP acknowledges and deeply respects the pioneering work of the Therapeutic Goods Administration (TGA) in establishing the MDMA and psilocybin Authorised Prescriber scheme. This initiative marks an historic step forward in expanding treatment options for people living with treatment-resistant mental health conditions and reflects the TGA's unwavering commitment to patient safety, public health, and regulatory excellence.

In recognition of this work, AMAPP offers this submission as a considered and constructive response to the Select Stakeholder Review Document. Our intention is to build upon the strong foundations already laid, addressing systemic issues experienced by practitioners and patients and identifying pathways to further enhance safety, access, and clinical quality. While our advocacy is firm in highlighting opportunities for improvement, it is grounded in respect, shared purpose, and a commitment to collaborative progress.

1.3 Scope of This Submission

The current recommendations pertaining to eligible practitioners under the Therapeutic Goods Administration (TGA)'s Approved Prescribers (AP) Scheme pose systemic risks, regulatory oversights, and ethical concerns in the field of PAP. This paper seeks to respond to TGA's Targeted External Consultation Paper, inclusive of:

- A clinical and policy analysis of the current implementation
- Evidence from international trials and Australian practice
- A detailed overview of AMAPP's training and credentialing standards including provisional, fully accredited and psychedelic assisted psychotherapy supervisor credentialing
- Clear, actionable recommendations to expand recognition under regulatory oversight

2. Level of Authorised Prescriber (AP) Oversight and Psychiatrist Experience

2.1 Question 1

Do you agree that the psychiatrist must have prior psychedelic-assisted psychotherapy clinical trial experience or requires initial supervision by an Australian-registered psychiatrist with experience in psychedelic-assisted psychotherapy?

Yes. Due to the complexity and risks associated with psychedelic-assisted psychotherapy (PAP), Authorised Prescriber (AP) psychiatrists should have a solid foundation of clinical experience in psychiatry, including exposure to trauma, mood disorders, and complex mental health presentations (RANZCP, 2025).

2.2 Question 2

If not, then please outline what experience or qualifications you believe are appropriate and your rationale to support your response.

The recommended level of experience is that the psychiatrist has completed Fellowship with the Royal Australian and New Zealand College of Psychiatrists (RANZCP), or possesses equivalent specialist psychiatric experience. This ensures the prescriber has developed adequate clinical judgment, is familiar with risk management, and is competent in supervising multidisciplinary teams (TGA, 2023).

3. Therapy Dyad Qualifications

3.1 Question 3

Should Ahpra-registered and qualified therapists trained in psychedelic-assisted psychotherapy, other than the following, be considered for the lead therapist role within a therapy dyad? a. Specialist psychiatrists registered with Ahpra; OR b. Clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology.

No, we do not believe that both members of the therapy dyad should be limited to practitioners regulated by the Australian Health Practitioner Regulation Agency (AHPRA). While ensuring safety and competence is essential, the lead therapist role should not be restricted solely to psychiatrists or endorsed clinical psychologists. In our view, qualified and appropriately trained therapists in psychedelic-assisted psychotherapy, including those with alternative but robust qualifications, should also be considered for this role.

3.2 Question 4

If so, what types of health practitioners should be considered for the lead therapist role and why?

The types of health practitioners who should be considered for the lead therapist role and the rationale for their inclusion, are outlined in following sections. This includes an examination of the current limitations of the TGA's Authorised Prescriber Scheme and recommendations for amending existing requirements. Our position advocates for expanding eligibility to include appropriately trained and experienced therapists who may not fall within the current AHPRA-regulated categories but possess the necessary competencies to ensure safe and effective delivery of PAP.

3.2.1 Excluding Psychotherapists from Psychedelic-Assisted Psychotherapy

At the heart of TGA's current policy framework for Psychedelic-Assisted Psychotherapy (PAP) in Australia lies a fundamental contradiction: despite the designation of the treatment as PAP, psychotherapists themselves are not recognised as eligible facilitators or co-therapists under the current regulatory implementation (refer to Appendix A for a table of the health, mental health, and social care practitioners referenced in this submission) . While safety is

paramount, current interpretations of eligibility may inadvertently limit access to qualified practitioners whose skillsets are well-aligned with the relational demands of psychedelic-assisted psychotherapy. Instead, the policy reflects an outdated model of discipline-based credentialing that fails to account for real-world competence, therapeutic outcomes, or the diversity of the workforce delivering these interventions in practice.

It is no coincidence that many of the clinicians who have led psychedelic therapy in Australia and who continue to train others are not only psychiatrists or psychologists, but psychotherapists. These psychotherapists include those involved in the earliest Australian psychedelic trials, senior trainers with the Multidisciplinary Association for Psychedelic Studies (MAPS) and Certificate of Psychedelic Assisted Therapy (CPAT) programs, and clinical supervisors in the AMAPP framework. The current TGA framework raises concerns about the exclusion of key theorists, researchers, and practitioners. The practice of PAP within Australia would be severely diminished by the exclusion of the expertise these professionals have to offer. Across Australia, psychotherapists are:

- Leading the clinical training and professional development of emerging psychedelic therapists;
- Supervising multidisciplinary clinical teams engaged in active PAP delivery;
- Serving as site investigators and therapy leads on clinical trials;
- Providing direct therapeutic care to clients in psychedelic and altered state contexts, often with decades of experience in transpersonal and integrative modalities.

Examples of Psychotherapists working in the PAP field:

- Dr. Traill Dowie, Associate Professor of Psychotherapy, co-lead on a major Australian clinical trials and co-author of Australia's first PAP training curriculum.
- Sean O'Carroll, former Head of Psychotherapy at Clarion Clinics, lead therapist and trainer at Monash Psychedelics Lab.
- Lana Sciberras, Monash Psychedelics Lab Psychotherapist
- Tara Green, Monash Psychedelics Lab Psychotherapist
- Sarah Pant, Monash Psychedelics Lab Psychotherapist
- Marg Ryan, Monash Psychedelics Lab Psychotherapist
- Steve Schwartz, ANU clinical Trial Psychotherapist

- Susan Jenkin, ANU clinical Trial Psychotherapist

Unlike traditional talk therapy, psychedelic-assisted practice requires expertise with non-ordinary states of consciousness. These phenomena cannot be managed with prescriptive symptom-checklists or cognitive models alone. They require the clinical presence, psychological depth, and emotional resilience that are hallmarks of advanced psychotherapeutic training. Moreover, the current regulatory stance minimises those clinicians with the most experience in these domains. Under TGA's present guidelines a junior psychologist with a clinical credential and minimal post-registration experience is eligible to sit alongside a client in a high-stakes psychedelic session. This stance excludes not only psychotherapists and counsellors but also psychologists with non-clinical standing. In contrast, psychotherapists with significant experience, despite having relevant competencies, thousands of hours of dyadic practice, and specialised trauma training are not currently eligible under the scheme. Poor attunement, failure to recognise boundary ruptures, or mismanagement of transference phenomena in PAP can have lasting psychological consequences. The clinical literature repeatedly shows that the quality of the therapeutic relationship and the specialised ability of the therapist is the most significant predictive factor in successful clinical outcomes, more so than the therapist's disciplinary title (Horvath & Bedi, 2002; Del Re, et al., 2012; Schwartz et al., 2025; Tschuschke et al., 2020). The TGA's current stance contradicts emerging international norms (Wampold, 2015). Countries such as Canada, the Netherlands, Israel, and U.S. states like Oregon have adopted competency-based credentialing frameworks for PAP that include psychotherapists, social workers, and other non-medical professionals, provided they complete accredited psychedelic psychotherapy training (College of Physicians & Surgeons of Alberta, 2023; Health Canada, 2023; Oregon Health Authority, 2023; Inwardbound Institute, 2025). These models reflect a growing consensus that PAP is not a pharmaceutical intervention, but a relational and experiential process requiring deeply specialised care. Allowing all qualified practitioners to contribute their specific expertise would strengthen safety, widen access, and align Australia's approach with international best practice (Canadian Psychedelic Association, 2025).

3.2.2 Oversight and Regulatory Architecture of Psychotherapy and Counselling

A recurrent critique in policy deliberations is that psychotherapists and counsellors are not AHPRA-registered and therefore, it is assumed, operate without adequate oversight. This assumption is inaccurate and overlooks the well-established regulatory architecture governing

these professions. In practice, psychotherapists, counsellors and social workers in Australia are subject to stringent ethical codes, transparent complaints processes, and mandated professional development requirements under national peak bodies such as the Psychotherapy and Counselling Federation of Australia (PACFA), the Australian Counselling Association (ACA), and Australian Association of Social Workers (AASW). It is important to emphasise that the absence of these professions from AHPRA's National Registration and Accreditation Scheme is not a regulatory gap but the outcome of a deliberate and repeatedly reviewed risk assessment by the Australian Health Ministers Advisory Council (AHMAC). Under the Health Practitioner Regulation National Law Act, a profession is included in AHPRA only when there is clear evidence that the risk of harm to the public cannot be managed by other mechanisms. Psychotherapy and counselling have been consistently judged as low-risk precisely because of the effectiveness of their existing complaint and disciplinary systems (Australian Health Ministers' Advisory Council, 2020).

PACFA, ACA, and AASW each maintain oversight systems that are functionally equivalent to those of AHPRA boards. All three enforce ethical codes, require continuous professional development (CPD), mandate clinical supervision, and operate formal complaints processes. However, it is worth noting there are meaningful differences in the structure, recognition, and regulatory rigour between PACFA, ACA, and AASW (refer to Appendix A for an overview of the registered professionals of AHPRA, PACFA, ACA, and AASW referred to in this submission. Refer to Appendix B for a detailed comparison of membership categories and governance frameworks).

PACFA enforces a detailed *Code of Ethics* (PACFA, 2022a) and oversees a formal complaints process through an independent Ethics Committee. Investigations follow a structured sequence: preliminary assessment, written submissions from parties, mediation options, and where necessary disciplinary panels with the authority to impose sanctions including suspension or cancellation of membership. Outcomes are reportable and in serious cases made public. PACFA (2022b) and AASW also mandates continuous professional development as a prerequisite for ongoing clinical membership, (a minimum of 20 hours annually) and regular clinical supervision (at least 10 hours per 12 months), ensuring active oversight throughout a practitioner's career. ACA (2023) members must maintain regular supervision, meet defined CPD thresholds, and are subject to disciplinary processes including independent adjudication, mandated retraining, or deregistration from the association. PACFA

is a full member of Allied Health Professions Australia which ensures that all registrants are recognised as Allied Health professionals and have appropriate tertiary training. PACFA is a qualifying member of the National Alliance of Self-Regulating Health Professions (NASRHP, 2020) which has strict requirements for membership rigor, accreditation independence and organisational governance which are best practice for the Australian Allied Health sector. This includes ensuring adherence to a Code of Ethics, annual CPD and supervision requirements, a formal audit process of 5.5% of registrants annually and management of grievances from the public using a comprehensive Professional Conduct Procedure.

AMAPP's proposed credentialing framework (as outlined in 3.2.7 AMAPP Credentialing Model of this document) reinforces and amplifies existing protections. Under AMAPP's model practitioners are eligible to serve as psychedelic-assisted psychotherapists or facilitators only if they are:

- Accredited with APHRA, PACFA or ACA (or other recognised professional bodies)
- Actively engaged in mandated supervision and CPD
- And have completed rigorous psychedelic-specific training

This creates a dual layer of accountability: first through the practitioner's primary regulatory body and second through AMAPP's own accreditation and supervision structures all operating within HREC-approved protocols and under the statutory responsibility of an Authorised Prescriber

Psychedelic-assisted psychotherapy is not a domain that should be monopolised by any single discipline. Each major modality of psychological practice carries distinct strengths and limitations. The question of qualification should not be whether someone holds a specific professional title, but whether they have acquired sufficient specialist training to work safely and effectively in this complex therapeutic modality. The TGA should therefore look to credentialing bodies that provide leadership in specialist training, rather than making ill-informed determinations based solely on the practitioner's profession. Globally, best practice has shown that psychedelic-assisted psychotherapy is practiced most safely and effectively when delivered by complementary, highly skilled, interdisciplinary teams. Failing

to adopt this approach is to take unnecessary risks with patient well-being, undermine the efficacy of treatment, and limit much needed access to treatment through limitations of scalability due to financial constraint.

3.2.3 Overreliance on Psychiatrists and Psychologists

The Therapeutic Goods Administration's (TGA) current implementation of the Authorised Prescriber (AP) scheme for MDMA and psilocybin therapy has the potential to entrench a restrictive clinical model without revision. Though not explicitly required in law, the policy framework has been interpreted to mean by many that only psychiatrists and clinical psychologists are eligible to deliver psychedelic-assisted psychotherapy (PAP), or to oversee those who do. This interpretation has had widespread and deleterious consequences for workforce planning, equitable access to care, cultural responsiveness, and clinical innovation.

There are a limited number of psychiatrists and clinical psychologists with both the interest and the capacity to take on PAP work. According to the Australian Institute of Health and Welfare (2022), the distribution of these professionals is heavily skewed toward urban centres. In rural and regional Australia where rates of trauma, suicidality, and treatment-resistant mental illness are often higher the availability of eligible prescribers or facilitators is exceptionally limited. Patients in these communities are effectively denied access to PAP not because the treatment is unsafe or inappropriate, but because there are not enough psychiatrists or clinical psychologists with the interest, training, or time to deliver it.

Additionally, the current restrictions in effect exclude many of the country's most experienced and appropriately trained psychedelic facilitators. These are professionals who have completed internationally recognised training programs (e.g., MAPS, California Institute of Integral Studies [CIIS], CPAT), worked in clinical trials, undergone supervision, and participated in hundreds of hours of experiential learning and integration practice (MAPS, 2022; California Institute of Integral Studies, 2023; Centre for Psychedelic-Assisted Therapies, 2023). Yet, unless they hold a specific disciplinary title, typically clinical psychologist or psychiatrist, they are deemed ineligible to participate in therapeutic delivery. This system disregards competency and substitutes it with credentialism. This leads to a core systemic flaw: access to this therapy is being governed by profession, not clinical readiness or safety outcomes. There is no other therapeutic modality in mental health care where eligibility to deliver treatment is so narrowly confined to two disciplines. Trauma-focused

therapy, grief work, somatic therapy, and group psychotherapy: all domains highly relevant to PAP are legally provided by a variety of qualified professionals in Australia and ethically practiced by a wide range of credentialed health professionals, including social workers, counsellors, psychotherapists, nurses, and others. The TGA’s own guidance (13 February 2023, updated 24 September 2024) does provide some latitude. It states:

The TGA expects that the HREC reviewing the treatment protocols would consider the training and experience of all staff involved in the treatment. It is likely that a minimum standard of training of others involved in patient oversight would be that of clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology or equivalent.

The use of terms like “*likely*” and “*equivalent*” creates interpretive ambiguity that in practice operationalises exclusion. The Human Research Ethics Committees (HREC) committees, out of caution or uncertainty, often defer to the strictest interpretation, one that privileges psychiatry and clinical psychology, even in the absence of PAP-specific expertise.

Further, the guidance continues:

The protocol should include details of the informed consent obtained, including consideration of the risks associated with these treatments. These aspects of the treatment protocol are likely to be very similar to the protocols that have recently been used in Australia and internationally in clinical trials of these substances.

Yet, internationally, clinical trial protocols, particularly those under MAPS, Imperial College, and other leading research bodies, routinely involve co-facilitator dyads where neither therapist is a clinical psychologist or psychiatrist. Instead, teams often include psychotherapists, nurses, social workers, and spiritual care providers whose primary qualifications are in relational psychotherapy, trauma-focussed care, and experiential therapy—the core competencies needed to manage non-ordinary states. Thus, there is a disconnection between the TGA’s stated reliance on international clinical protocols and the local interpretation of facilitator eligibility. If Australia is to adopt trial-aligned delivery models, it must also recognise the trial-aligned credentialing frameworks used abroad;

frameworks that are multidisciplinary, competency-based, and inclusive by design. The solution is not to lower standards, but to clarify them.

3.2.4 Comparative Training: Psychology vs. Psychotherapy

The decision to privilege clinical psychologists in the delivery of psychedelic-assisted psychotherapy overlooks an appropriate comparison of the training undertaken by other treating professionals. According to the Australian Psychology Accreditation Council (APAC, 2019), graduates of accredited postgraduate psychology programs must complete a minimum of 1,000 placement hours for a master's degree, which includes at least 400 hours of direct client activities (DCA), and up to 1,500 hours including 600 hours of DCA at the doctoral level. These placements generally emphasise structured, time-limited interventions rooted in diagnostic assessment and cognitive-behavioural therapy models. While this structured model offers a solid foundation for conventional mental health interventions, it does not necessarily prepare practitioners to engage with the complexity and unpredictability of non-ordinary states of consciousness, symbolic regression, or somatic-emotional releases common in psychedelic-assisted psychotherapy.

PACFA registered psychotherapy and counselling professionals have completed alternative training pathways which prioritise the development of deep philosophical understanding of relationship, therapeutic engagement. This university level training completed at Bachelor or Postgraduate levels includes core counselling curriculum as well as specialisations addressing specific cohorts, modalities and settings to ensure achievement of key professional competencies. Many counsellors undertake counselling training as a second career and nearly 50% of PACFA registrants have previously completed psychology, social work, nursing or teaching qualifications. Psychotherapy training is completed at an advanced level (AQF 9) in addition to the counselling training required for registration and covers: best practice, theoretical and experiential knowledge and skills, assessment and evaluation, psychotherapeutic interventions, the psychotherapeutic relationship, supervision and reflective practice as identified in the competencies for a Registered Clinical Psychotherapist (publication forthcoming).

PACFA accredited counselling training is assessed to meet core requirements across five domains: public safety, academic governance and quality assurance, program study, the

student experience and assessment. Outputs measured include completion of a significant placement as well as supervision in training. This training ensures that PACFA registrants have sufficient training to practice safely as Allied Health professionals in all healthcare settings including psychedelic assisted therapy, when additional setting-specific training is provided.

Furthermore clinical psychotherapy registration requires an additional 450 hours of advanced clinical training. These training standards prioritise long-term relational engagement, depth oriented psychological practice, trauma integration, and somatic processing—all of which are competencies highly relevant to psychedelic therapy. The discrepancy in training hours often cited to justify the preferential treatment of clinical psychologists does not hold up under closer scrutiny. When post-qualification clinical experience is included, many PACFA and ACA accredited practitioners have undergone comparable client-facing hours and within a framework congruent with the therapeutic mechanisms of psychedelic treatment. These include sustained relational contact, symbolic and emotional integration, and somatic-emotional attunement (refer to Appendix B for a detailed overview of counselling and psychotherapy training pathways and practitioner readiness for psychedelic-assisted psychotherapy).

Psychedelic-assisted psychotherapy is fundamentally different from standard short-term or manualised interventions. It frequently involves the re-experiencing of trauma, altered states of identity and consciousness, existential insights, emotional processing, and the need for careful symbolic meaning-making. The capacity to hold and understand complex affective states, support clients through psychological disintegration and reintegration, and to work within expanded states of consciousness are not inherent to any single profession. They are competencies developed through training, experience, and supervision which AHPRA, PACFA and ACA standards explicitly foster. A commitment to public safety and clinical excellence demands that these competencies must guide eligibility to deliver psychedelic-assisted psychotherapy. Restricting access based on professional title, rather than demonstrated specialist education and capability, may inadvertently disqualify clinicians with highly relevant training and experience.

3.2.5 Honouring Diversity and Inclusion in Psychedelic-Assisted Psychotherapy

AMAPP recognises that effective psychedelic therapy in Australia could best acknowledge, support, and honour Indigenous models of care. The current regulatory framework fails to acknowledge Indigenous knowledge systems and their deep and longstanding relationship with plant medicines (Dudgeon et al., 2014; PACFA, 2022a). AMAPP's accreditation standards allow for the formal recognition of First Nations healthcare practitioners who provide culturally informed trauma integration and community-led healing practices (AMAPP, 2025). These practitioners offer essential insight into holistic, place-based, and relational models of care. These traditions have a long-standing knowledge and appreciation of psychedelic medicine which, when contextualised within a clinical framework such as PACFA's *Indigenous Healing Practice Training Standards*, may provide utility to furthering clinical applications of PAP (PACFA, 2021a). Excluding Indigenous practitioners with requisite clinical qualifications not only perpetuates cultural injustice but severely limits the therapeutic possibilities of psychedelic treatment in Indigenous contexts. For PAP to be ethical and effective in Australia it must allow for multidisciplinary perspectives overseen and held within a tight regulatory framework.

The PACFA Indigenous Healing Practice Training Standards (2021b) include a figure depicting the “8 Key Features of Indigenous Healing Practice” or eight domains—framed as foundational for training standards and registered practitioners.



Beyond cultural inclusion, diversity in practitioner backgrounds and experiences is often undervalued and rarely sought out intentionally. PAP dyads should include not only skilled practitioners who meet all regulatory, experiential, and training requirements but also qualified individuals from diverse backgrounds that enrich and support the PAP environment. Examples include spiritual and religious leaders, cultural practitioners, music and art therapists, end-of-life nurses, and First Nations people, all of whom hold recognised qualifications and meet AMAPP's credentialing framework (outlined in section 3.2.7 AMAPP Credentialing Model).

3.2.6 International Evidence and Standards

3.2.6.1 Clinical Trial Configurations: Global Precedents: Evidence from International Clinical Trials.

A compelling body of international evidence now exists that supports the safe, ethical, and effective use of multidisciplinary dyads in psychedelic-assisted psychotherapy (PAP). Clinical trials conducted under rigorous regulatory and ethical scrutiny, including those undertaken by MAPS in the United States and Israel, Imperial College London in the UK, Health Canada, and national research bodies in the Czech Republic and Australia, consistently demonstrate that the professional composition of therapist dyads is less important than their training, supervision, and clinical competency. Across dozens of trials between 2021 and 2024, facilitator dyads have frequently included non-clinical psychologist professionals, such as psychotherapists, counsellors, registered nurses, general practitioners, social workers, and spiritual care providers, provided they had completed protocol-specific psychedelic therapy training and ongoing supervision (MAPS Israel, n.d.; MAPS Public Benefit Corporation, 2023; Páleníček et al., 2022; Tai et al., 2021; The Australian, 2023). These facilitators were assessed not on the basis of discipline or registration board, but on their demonstrated ability to uphold safety, and work competently with non-ordinary states of consciousness. For example:

- In MAPS-sponsored MDMA trials (Phase 2 and 3, 2021–2023), dyads routinely consisted of a psychologist paired with a counsellor, psychotherapist, or nurse. These practitioners received targeted training via the MAPS Therapist Training Program, which emphasises trauma-informed care, transference management, and somatic awareness, rather than relying on discipline-specific licensure (Tai et al., 2021).

- In Israel, clinical dyads in both MAPS trials and expanded access programs have consistently included psychotherapists, social workers, psychologists, and nurses. These teams were trained in alignment with MAPS protocols and outcome metrics, including Clinician-Administered PTSD Scale (CAPS-IV) and Global Assessment of Functioning (GAF) scores, and demonstrated high rates of improvement in patients with treatment-resistant PTSD (MAPS Israel, n.d.).
- In the Czech Republic, all registered psychedelic-assisted psychotherapy dyads—100% of them—include non-psychologists. They often combine body psychotherapists or Jungian therapists with trained nurses or psychiatrically informed counsellors. These professionals were trained through MAPS-approved curricula and have delivered outcomes on par with or exceeding those of conventional mental health teams. These trials are often hosted in state hospitals or affiliated research centres and are subjected to full national ethical review processes (Páleníček et al., 2022).
- In Canada, under both the Special Access Program (SAP) and ongoing research projects, dyads frequently include registered psychotherapists, spiritual care providers, and First Nations cultural practitioners. In several Health Canada–approved trials, Indigenous healers have been embedded in dosing and integration phases, reflecting a broader shift toward culturally contextualised models of care (MAPS Public Benefit Corporation, 2023).
- In Australia, early-phase PAP research trials have also employed dyads of practitioners who are not solely psychologists and psychiatrists. These include therapists trained in somatic psychotherapy, integrative trauma modalities, and psychodynamic practice, most of whom do not carry clinical psychology endorsements. These trials have received HREC approval and are yielding strong therapeutic alliances and retention rates (The Australian, 2023).

This growing corpus of evidence decisively challenges the notion that clinical psychology or psychiatry credentials are necessary, or even optimal, for all co-facilitators of psychedelic therapy. What the data shows instead is that the core determinants of safety and efficacy are:

- Protocol-specific training
- Clinical supervision
- Ethical clarity

- And therapist presence, attunement, and cultural sensitivity

These findings are not peripheral as they attest to the fundamentals of how psychedelic psychotherapy should be implemented: not as a pharmacological procedure delivered by diagnosticians, but as an embodied, relational, and often transpersonal process supported by clinicians trained in depth-oriented, trauma-informed, and integrative modalities. Despite this clear international precedent, Australia's current AP scheme narrowly interprets eligibility, effectively excluding the very kinds of practitioners who have proven successful in global trials. This position isolates Australia from the evolving international standard and risks creating a two-tiered system: one for clinical trials (which allow flexibility), and another for clinical practice (which enforces rigidity). The TGA's current guidance notes that clinical trial protocols should inform real-world implementation. If that is to be taken seriously, then the multidisciplinary configurations that have succeeded internationally must be enabled locally. Australia now stands at a crossroads. It can continue down a path of exclusionary credentialism, one unsupported by global data, or it can embrace the inclusive, evidence-based model, one which international research has already proven to be safe, effective, and scalable.

3.2.6.2 Existing Training Frameworks

The safe, ethical, and effective delivery of psychedelic-assisted psychotherapy (PAP) demands more than regulatory oversight; it requires a deeply rooted commitment to clinical integrity, therapeutic attunement, and evidence-based training. Australia's current implementation of PAP under the Authorised Prescriber scheme continues to rely heavily on professional titles, privileging psychiatrists and clinical psychologists. However, this approach is increasingly out of step with international best practice. A growing body of global research and clinical training experience led by organisations such as the Multidisciplinary Association for Psychedelic Studies (MAPS, 2022), Fluence (2024), and BrainFutures (2023), has firmly established that competency, not professional designation, is the appropriate benchmark for involvement in psychedelic therapy.

The MAPS MDMA Therapy Training Manual, developed by Mithoefer (2017), remains the most widely adopted and influential framework for training psychedelic therapists. This model welcomes clinicians from a broad spectrum of disciplines, including psychotherapists, social workers, nurses, and spiritual care providers. MAPS does not restrict eligibility based

on professional title but instead focuses on the ability of practitioners to develop and apply core clinical competencies. These competencies include trauma-informed care, somatic awareness, ethical containment of non-ordinary states, and symbolic and transpersonal integration. These capacities form the foundation of safe and effective psychedelic-assisted psychotherapy and are found across multiple professions, not exclusively within psychiatry or psychology.

Fluence, a US-based training organisation aligned with the MAPS framework furthers this inclusive ethos. Its programs emphasise the relational, process-based nature of psychedelic work, training practitioners in harm reduction, integration, and ketamine-assisted psychotherapy. Fluence encourages a therapeutic approach rooted in presence, humility, and culturally sensitive care. Rather than framing psychedelic psychotherapy as a procedure to be delivered, Fluence teaches that this work is fundamentally about co-creating spaces of transformation where clients can engage meaningfully with their inner landscapes and initiate self-directed healing. Their comprehensive curriculum includes trauma-informed practice, spiritual emergence, therapist self-care, ethical awareness, and integration techniques.

3.2.7 AMAPP Credentialing Model

Recognising these global benchmarks, AMAPP has established an accreditation and credentialing framework tailored to Australia's unique clinical and cultural landscape. This framework is presented below and outlined in AMAPP's [Accreditation Guidelines](#) (AMAPP, 2025) and [Supervision Guidelines](#) (AMAPP, 2024). The AMAPP model balances international training standards with local regulatory realities and the imperative for cultural responsiveness, recognising the diverse and complementary competencies across disciplines and backgrounds to provide a viable and evidence-aligned model for ensuring clinical readiness. At the heart of this framework is a tiered practitioner model that accommodates the varying responsibilities and contributions of professionals working in therapy dyads.

AMAPP's model builds directly on MAPS and certificate in psychedelic assisted psychotherapy frameworks, and is aligned with this global consensus. It ensures that all co-therapists, regardless of professional origin meet a high threshold for training, supervision, ethical conduct, and clinical readiness. With tiered roles, minimum training hours, supervision requirements, and credentialing oversight, AMAPP's framework offers a robust mechanism to determine facilitator eligibility based on demonstrated readiness rather than professional title alone.

To promote both safety and equity in this emerging field, Australia’s regulatory approach must move toward a model of approximate parity where training hours, supervision, and competency benchmarks are evaluated across professions—not used to entrench existing hierarchies. This would align with international practice, honour the full scope of clinical expertise available, and ensure that clients receive care from therapists with the specific skills required to guide transformative and sometimes destabilising psychedelic journeys.

AMAPP’s model extends beyond professional regulation to encompass a relational ecosystem of care. At the operational level, all PAP delivery must occur in a dyadic structure. Each dosing session must include at least one Psychedelic-Assisted Therapist, with a second co-facilitator who may be either another PAP or a Psychedelic Facilitator. At least one member of this dyad must hold current AHPRA registration, ensuring clinical oversight and legal accountability. This dyadic approach enables complementary pairings that honour both clinical rigour and cultural fit. For instance, a psychologist with PAP training might co-facilitate alongside a psychotherapist, a nurse, or a paramedic. These combinations bring diverse skills to the therapeutic space and allow for a more responsive, inclusive model of care. In this way, AMAPP’s framework enhances accessibility, maintains ethical safety, and honours the collaborative nature of psychedelic healing. By adopting AMAPP’s training and credentialing standards as the national benchmark the TGA has the opportunity to establish a best-practice model that reflects the diversity of clinical expertise in Australia, one which ensures ethical delivery, and honours cultural and spiritual dimensions of care. It moves the regulatory framework away from exclusionary credentialism and toward a future of psychedelic therapy defined by integrity, best practice, science, and training.

3.2.7.1 Core Roles Defined

1. Psychedelic Authorised Prescriber (AP):

The psychedelic authorised prescriber is typically a psychiatrist with PAP-specific training who holds Authorised Prescriber status. This individual is responsible for assessing patient suitability, prescribing psychedelic medicines, and, where qualified, may participate in preparation and integration processes.

2. Psychedelic-Assisted Therapist (PAT):

The psychedelic assisted therapist (PAT) is a clinician from psychotherapy, psychology, counselling, or social work backgrounds who has completed PAT-specific

training and is responsible for the full therapeutic arc: preparation, support during the dosing session, and ongoing integration work.

3. **Psychedelic Facilitator (PF):**

The psychedelic facilitator is a co-therapist who supports preparation and dosing, often with experience in nursing, paramedicine, pastoral care, or Indigenous health. While not always leading therapy, Facilitators provide critical emotional and cultural support under supervision.

4. **AMAPP-Accredited PAP Supervisor:**

An AMAPP-Accredited Supervisor is qualified to oversee trainee therapists or facilitators through supervised practice. Supervisors hold appropriate credentials (e.g., psychologist, psychiatrist, psychotherapist), have completed multiple dosing sessions, and meet supervisory standards.

3.2.7.2 Accreditation

The process of recognising a practitioner as qualified to practice PAP as a Psychedelic-Assisted Therapist (PAT) or Psychedelic Facilitator (PF)

- I. **Provisional accreditation:** Practitioner is receiving training and supervision
- II. **Full accreditation:** Education and supervised experience requirements met
- III. **Dosing session:** A full psychedelic medicine session from arrival to departure

3.2.7.3 Pathways to Accreditation

Three practitioner types:

- 1. Psychedelic Prescriber (PP)
- 2. Psychedelic-Assisted Therapist (PAT)
- 3. Psychedelic Facilitator (PF).
- 4. AMAPP Accredited PAT supervisor

Accreditation status (Provisional vs Full) is based on training and experience.

3.2.7.4 Role Definitions

- 1. **Psychedelic Prescriber:** Psychiatrist or medical practitioner with PAT training and prescribing authorisations.

2. **Psychedelic-Assisted Therapist:** Practitioner conducting all stages of therapy (preparation, dosing, integration).
3. **Psychedelic Facilitator:** Co-therapist supporting sessions under supervision.

3.2.7.5 Therapy Dyads

Every dosing session must include at least one AHPRA accredited Psychedelic-Assisted Therapist, plus either a second PAT or a PF. At least one practitioner must hold current accreditation with a regulatory body. Authorised Prescriber, Nurse, Medical team are required on site as per HREC protocols.

AMAPP clarifies that it is not necessary for both therapists in the PAP dyad to attend every preparation and integration session. The lead PAP therapist is responsible for attending all phases of the process, including all integration sessions and selected preparation sessions, ensuring continuity and client safety. The secondary therapist/clinician must meet the client prior to the first dosing day as part of the therapeutic protocol and is required to attend **all medicine dosing sessions** alongside the lead therapist.

This model ensures both therapists are present for medicine day safety and therapeutic containment, while allowing flexibility in non-dosing sessions to reduce costs without compromising quality or client outcomes.

*Examples of Dyads:

- Dyad 1 – Psychologist (AHPRA) with PAT training + Psychotherapist with PAT training
- Dyad 2 – Psychotherapist with PAT training + Nurse (AHPRA) with PAT training
- Dyad 3 – Clinical Psychotherapist with PAT training + Paramedic (AHPRA) with PAT training
- Dyad 4 – Psychiatrist (AHPRA) with PAT training + Psychologist with PAT training
- Dyad 5 – Psychologist (AHPRA) with PAT training + Psychotherapist with PAT training
- Dyad 6 – Psychotherapist with PAT training + Psychiatrist (AHPRA) with PAT training
- Dyad 7 – General Practitioner (AHPRA) with PAT training + Psychotherapist with PAT training

- Dyad 8 – Accredited Mental Health Social Worker with PAT training + Psychotherapist with PAT training
- Dyad 9 – Paramedic (AHPRA) with PAT training + Accredited Mental Health Social Worker with PAT training
- Dyad 10 – Indigenous Health Practitioner or Aboriginal Health Worker (Medicare-approved for eligible Indigenous patients via specific MBS items 81300 etc.) with PAT training + Psychotherapist with PAT training
- Dyad 11 – General Psychologist (AHPRA) with PAT training + Psychotherapist with PAT training
- Dyad 12 – Clinical Psychologist (AHPRA) with PAT training + Counselling Psychologist (AHPRA) with PAT training
- Dyad 13 – Counselling Psychologist (AHPRA) with PAT training + Psychotherapist with PAT training
- Dyad 14 – Clinical Psychologist (AHPRA) with PAT training + Accredited Mental Health Social Worker (AMHSW, Medicare-approved) with PAT training
- Dyad 15 – General Psychologist (AHPRA) with PAT training + Indigenous Health Practitioner or Aboriginal Health Worker (Medicare-approved) with PAT training

*These examples of dyads would still operate within current TGA guidance, whereby therapy dyad roles and configurations are HREC-approved and under the statutory responsibility of an Authorised Prescriber. AMAPP's position is to advocate for a multidisciplinary therapy dyad.

3.2.7.6 Accreditation Standards

AMAPP credentials practitioners based on independent, policy-driven education standards informed by a systematic review of global competency frameworks for psychedelic-assisted therapy. Rather than being tied to any single university curriculum, our standards draw from internationally recognised clinical training domains, ethics, indigenous knowledge, somatic and trauma-informed practices, and a multidisciplinary professional base. This positions our accreditation around evidence-based knowledge and core competencies identified across contemporary research and professional models. This approach mitigates the risk of vested interests inherent in individual institutional programs and supports diverse learning pathways that reflect different practitioner strengths, cultural approaches, and regional contexts.

1. Core Training

Both Psychedelic-Assisted Therapists and Psychedelic Facilitators must have completed core training in Psychedelic-Assisted Psychotherapy with a minimum of 100 hours of theory/didactic learning demonstrating:

- Foundational knowledge: psychedelic history, the ‘Drug War’ and resurgence of research
- Indigenous wisdom: historical use of plant medicines and cultural context
- Pharmacology: psychedelic mechanisms and neuroscience
- Medical screening: contraindications, complexity, trauma-informed care
- Research: current Australian and global clinical evidence
- Ethics: safety, risk mitigation, relevant laws, professional guidelines
- Preparation and integration: clinical intake, set and setting, intention, mystical/transpersonal processes, somatic and trauma-informed integration, harm reduction, spiritual emergence, existential themes
- Space holding: non-directiveness, attunement, therapeutic touch, music and playlist curation
- Therapeutic relationship: boundaries, transference, counter-transference, therapist self-care

2. Experiential Training

- Minimum two years of clinical therapy experience
- Minimum 40 hours of experiential learning (breathwork, role play, dosing)
- Facilitation of at least two dosing sessions under supervision, e.g., clinical trials or community cannabis/ketamine work
- Supervision signed off by a PAT-experienced supervisor (minimum six hours) or confirmed by letter and peer reference verifying safe delivery across preparation, dosing, and integration.

3. Personal Development Work

Significant engagement in personal therapy, reflective practice, and legal non-ordinary state work (e.g., breathwork, meditation) to support therapist development.

4. Professional Registration

Registered with a governing body such as:

- Australian Health Practitioner Regulation Authority (AHPRA)
- Australian Association of Social Workers (AASW)
- Psychotherapy and Counselling Federation of Australia (PACFA)
- Australian Counselling Association (ACA)

5. Professional Insurance

All multidisciplinary psychedelic professionals must maintain their own professional indemnity insurance or be appropriately covered under the insurance policy of a licensed clinic, research institution, or university trial in which they are working.

6. Complementary Therapeutic Modalities

Background training in psychology, psychotherapy, or counselling plus capability with trauma-informed and somatic modalities, including:

- Somatic (e.g., EMDR, Hakomi, Sensorimotor Psychotherapy, Somatic Experiencing)
- Trauma-informed multiplicity models (e.g., Internal Family Systems, Structural Dissociation, Ego State Therapy, Resource Therapy, Gestalt, Jungian Depth Psychology, Schema Therapy, Transpersonal Psychology, Voice Dialogue, Emotion Focused Therapy)
- Mindfulness-based (e.g., ACT, DBT, MIBT)

7. Therapist Characteristics

Applicants must demonstrate:

- Good personal character and ethical integrity
- Professional registration
- Respect for Australian law regarding psychedelic use
- No outstanding allegations of abuse or misconduct
- Adherence to AMAPP Code of Conduct

8. Aboriginal and Torres Strait Islander Practitioners

AMAPP recognises Indigenous knowledge systems and supports culturally safe accreditation pathways, including practitioners and support workers using culturally informed healing practices such as:

- Narrative therapy
- Grief and loss counselling
- Indigenous counselling training
- Trauma integrated healing approaches

9. Continuing Professional Development

Ongoing professional development and supervision to maintain competency in psychedelic-assisted psychotherapy.

10. AMAPP-Accredited Supervisor Supervision Guidelines

Supervised practice may involve video-recorded sessions or co-therapy. To qualify as an AMAPP-Accredited Supervisor, an individual must have:

- Credentials in therapy (e.g., psychologist, psychiatrist)
- Minimum two years supervisory experience
- At least four dosing sessions delivered over 12 months
- Experience across all preparation, dosing, and integration phases

Once two dosing sessions and six hours of supervision are completed, the supervisor provides a letter confirming eligibility for full practitioner accreditation.

3.2.7.7 AMAPP Credentialing Processes/Framework

The credentialing requirements for these roles are rigorous. All accredited practitioners must complete a minimum of 100 hours of didactic learning, covering foundational topics such as psychedelic research history, ethno-medicine, pharmacology and neuroscience of psychedelic agents, trauma-informed screening, ethical guidelines, risk management, and core preparation and integration strategies. Additional instruction is provided in somatic and transpersonal approaches, symbolic processing, and therapeutic boundaries. These curricula draw on international sources, including MAPS (2022), BrainFutures (2023), and Fluence (2024), but are refined to reflect Australian clinical standards and cultural needs. For instance, AMAPP integrates modules on ethno-medicine, grief and loss in community, and ecological models of

care, acknowledging the importance of local knowledge systems. Experiential learning is also a key requirement. Candidates must have at least two years of clinical therapy experience and complete more than 40 hours of experiential training through breathwork, role play, and supervised PAT sessions.

Full accreditation:

Full accreditation requires participation in at least two supervised dosing sessions, such as those in clinical trials or community-based ketamine therapy, and six hours of one-on-one supervision with a PAT-experienced clinician. To confirm readiness, applicants must also submit a written endorsement from a supervisor or co-therapist attesting to their competence in preparation, dosing, and integration.

Ethical integrity and personal development form the final pillar of AMAPP's framework. All practitioners must be registered with a relevant professional body, such as:

- Australian Health Practitioner Regulation Agency (AHPRA)
- Psychotherapy and Counselling Federation of Australia (PACFA)
- Australian Association of Social Workers (AASW)
- Australian Counselling Association (ACA)

Candidates must also commit to ongoing personal reflection, therapy, and professional development. Regular supervision, ethical audits, and engagement with peer learning networks are not optional but foundational to maintaining accreditation.

4. Level of Authorised Prescriber Oversight

4.1 Question 5

Do you agree that, to provide the appropriate level of oversight to their patient, the AP psychiatrist must be physically on-site at the treatment location?

The AP psychiatrist must conduct all medical assessments, prescribe the psychedelic, and oversee the treatment plan.

4.2 Question 6

If not, what oversight structure do you consider to be appropriate, why and does this structure meet the requirements of an approved AP?

Direct presence throughout the dosing session is not always required if there is:

- a trained on-site therapy team, including at least one clinician authorised to administer Schedule 8 rescue medications (e.g., a registered nurse, nurse practitioner, authorised paramedic, or medical practitioner), and
- real-time telehealth access to the AP psychiatrist for immediate consultation and escalation if needed (MAPS, 2021; Johns Hopkins, 2018).

4.2.1 Workforce and Access Considerations

Australia faces a chronic and uneven distribution of the mental health workforce, a problem long documented by the Australian Institute of Health and Welfare (AIHW, 2022). While metropolitan areas continue to host the majority of psychiatrists and clinical psychologists the availability of these specialists declines precipitously in outer regional, remote, and very remote locations (RANZCP, 2025). According to AIHW data major cities have nearly doubled the number of mental health professionals per 100,000 population, compared to remote areas where workforce density is at its lowest (see Appendix C). In real and practical terms, this discrepancy translates into delays in access to care, fragmented care pathways, and a near-total absence of specialist-led interventions in many regional communities. This uneven access poses serious challenges for delivering equitable mental health care (Kavanagh et al., 2023). While populations living in rural and remote areas face higher rates of psychological distress and suicide, they also encounter greater systemic barriers when attempting to access care (National Rural Health Alliance, 2021; Flavel et al. 2024). The limited distribution of psychiatrists and clinical psychologists in these regions means that services reliant on their direct involvement, such as the current implementation for PAP, are functionally out of reach for much of the population.

The existing PAP framework under the Authorised Prescriber scheme mandates that treatment be delivered by or under the direct supervision of a psychiatrist. While this stipulation is sound, the inference that clinical psychologists should be those exclusively administering the psychotherapy is without evidential justification. While this suggestion

may appear to safeguard clinical quality, in addition to excluding clinicians who are effectively most qualified, it creates a service bottleneck that undermines both access and efficacy. Once again, it is assumed that clinical competence is synonymous with professional title. This disregards the growing body of evidence that demonstrates the effectiveness of multidisciplinary dyads in psychedelic therapy. This narrow regulatory stance impedes access to care in precisely the regions and populations where it is most needed: trauma-impacted individuals, culturally diverse communities, and those affected by chronic service under-resourcing. In contrast, AMAPP's model supports a broader, competency-based framework that would immediately improve equity and scale. By including credentialed therapists from a range of healthcare practitioners with relevant training, the system recognises the diversity of skilled professionals already working on the frontlines of mental health care. These practitioners are often those best placed to offer trauma-informed, culturally safe, and locally accessible care. Many of these clinicians already operate in regions underserved by psychiatrists and psychologists and have established trust within their communities. Expanding the eligibility for PAP facilitation in line with AMAPP's standards would alleviate workforce pressures and allow service delivery to grow without compromising clinical safety.

AMAPP-accredited practitioners are required to undergo rigorous training, experiential learning, ongoing supervision, and adhere to professional codes of conduct enforced by their respective registration bodies such as: AHPRA, PACFA, ACA, Australian Psychology Society (APS), Australian Association of Psychologists Inc. (AAPI), Australian Association of Social Workers (AASW). To endorse therapists from these organisations in no way undermines clinical governance, as the prescribing authority and overall responsibility would continue to reside with the Authorised Prescriber. Moreover, utilising workforce availability where it aligns with facilitator eligibility reflects a pragmatic and sustainable approach to system design. This enables task-sharing without compromising competency standards and allows communities to be served by professionals embedded in their contexts. In doing so, the strain on overburdened psychiatrists and clinical psychologists is relieved. The AIHW's findings present a compelling case for structural reform. Without inclusion of recognised PAP facilitators, the current system risks perpetuating existing problems of access to specialised care. AMAPP's model offers a scalable, ethical, and clinically rigorous pathway to broaden access while upholding the principles of safety, efficacy, and cultural relevance. If psychedelic-assisted psychotherapy is to play a meaningful role in Australia's mental health

strategy, it must be delivered by a workforce that is appropriately trained, available, and trusted by the communities it serves.

4.2.2 Access, Safety, and Clinical Governance

Expanding eligibility for participation in therapy dyads enhances access without compromising clinical safety. Under AMAPP's model, the prescription and administration of all psychedelic medicines remain under the authority of an Authorised Prescriber who is legally responsible for screening and risk management. These prescribers collaborate with multidisciplinary teams including nurses, counsellors, psychotherapists, psychologists to offer a model of care which is most likely to meet the complex needs of the client through personalised care planning (refer to Appendix D: Psychedelic Clinical Trial Therapist Configurations for examples of multidisciplinary configurations). Clients can be matched with therapists based on gender, cultural background, language, spiritual orientation, or lived experience. The facilitation of greater choice for the client is aligned with contemporary best practice in medicine which seeks to support and engender patient agency and autonomy in the care process. Facilitation of choice significantly increases the likelihood of a strong therapeutic alliance and is one of the most important predictors of treatment success. Furthermore, expanding the scope of recognised practitioners will decrease the strain on Australia's already overburdened psychology workforce.

Through the recognition of a clear multi-disciplinary approach to PAP, as proposed by AMAPP, clinical governance will be strengthened by the oversight of multiple professional peak bodies, each with intersecting ethical standards and codes of conduct. This model holds safety and access in dynamic tension, achieving both through intentional training, clear role definitions, and strong governance. The result is a more ethical, scalable, and inclusive system of care that honours both evidence and equity. In conclusion, the AMAPP Credentialing and Supervision Model offers a solution that addresses the gaps in Australia's current PAP policy by incorporating international standards for best practice and offering a flexible, competent, and ethically sound workforce strategy. It is for this reason that AMAPP implores the TGA to not only recognise this model but embed its standards into the national framework for psychedelic therapy delivery.

5. Appropriate Site Location

5.1 Question 7

Should sites other than day hospitals or inpatient settings be considered appropriate for an AP to provide the service of psychedelic-assisted psychotherapy through this scheme?

PAP should be delivered in flexible treatment settings beyond day hospitals and inpatient units. Approved settings should include:

- Accredited community-based mental health clinics and integrated mental health centres, where appropriate safety and governance requirements are met. This includes the presence of suitably trained teams and provisions for medicine storage.
- Private outpatient facilities with multidisciplinary teams (e.g., psychiatrist and therapist) and secure medicine management protocols.
- Hospital outpatient units, particularly for patients with complex medical needs, where access to multidisciplinary care is available.
- Regional and remote clinics that meet the same safety and governance criteria as metropolitan sites, to ensure equitable access for rural populations and reduce travel burdens.

Telehealth may support elements of care such as preparation and integration, especially in rural or remote settings. However, it is not recommended for the administration of dosing sessions. Addressing access disparities between metropolitan and rural areas is critical, given the ongoing failure of public funding to adequately support regional mental health infrastructure.

Research indicates that in psychedelic work, settings that are warm, welcoming, non-medical environments with home-like aesthetics and atmosphere contribute to deeper emotional processing and trust during the vulnerable states experienced (Watts et al., 2017). Cold environments may reactivate trauma, especially for clients with a history of hospitalisation or institutionalisation (Gorman et al., 2021). Broadening of site access with the requirement that all potential sites adhere to the same combined safety and appropriateness criteria, ensures the safe, ethical, and equitable delivery of PAP across a range of clinical environments (TGA, 2023; AMAPP, 2025).

5.2 Question 8

If so, please provide comments on appropriate criteria that would ensure a site is appropriate.

The current Authorised Prescriber (AP) scheme limits prescribing of MDMA-and psilocybin-assisted psychotherapy (PAP) primarily to psychiatrists. While psychiatrists have critical expertise in diagnosis and psychopharmacology, this approach significantly restricts workforce capacity and timely access—particularly in rural and regional areas.

1. Workforce Limitations

- Only a small number of psychiatrists are trained or interested in psychedelic-assisted psychotherapy.
- Many psychiatrists focus primarily on diagnosis and medication management and may have limited direct experience in the relational and experiential elements that are central to PAP.
- This creates potential bottlenecks in access, leaving patients waiting extended periods for assessment and treatment.

2. Specialist Skills of Other Medical Practitioners

- There is a broad range of non-psychiatrist medical practitioners—including GPs, addiction medicine specialists, pain and palliative care physicians, and emergency doctors—who already provide frontline mental health support and counselling.
- Many of these practitioners have undertaken or are undertaking specialist psychedelic therapy training and are well placed to integrate prescribing with holistic care.
- Their clinical experience in managing trauma, anxiety, and complex pharmacological regimens positions them as safe candidates for expanded prescribing authority, provided robust governance is in place.

3. Safety, Governance, and Credentialing

- Any consideration of expanding prescriber eligibility must include specialist training, adherence to clinical governance frameworks, and ongoing supervision.

- AMAPP credentialing standards provide a pathway to ensure that non-psychiatrist prescribers meet competency benchmarks in PAP and work within multidisciplinary teams.

4. Future Workforce Opportunities

- The introduction of Paramedic Practitioner roles (Victoria & NSW) and advanced nursing prescribers highlights a growing trend toward broadening specialist prescribing frameworks in Australia.
- Embedding these roles within psychedelic care, in accordance with AMAPP standards, would further strengthen workforce capacity, particularly for regional and remote communities.

Psychedelic-assisted psychotherapy (PAP) must be delivered in carefully designed clinical environments that meet high standards of infrastructure, safety, cultural appropriateness, and clinical governance. The following elements are required:

1. Physical Infrastructure & Room Quality:

- Therapy rooms must be:
 - Private, quiet, and soundproofed to minimise external noise.
 - Equipped with adjustable lighting, temperature control, and comfortable reclining chairs or beds.
 - Designed to support prolonged sessions (6–8 hours) and allow for rest and integration post-session.
 - Free from clutter, warm and welcoming, but without any imposed cultural or spiritual symbols unless selected by the client.
- Accessible toilet facilities must be adjacent to therapy rooms.
- Dedicated integration space for post-session debriefing and rest.
- Facilities must accommodate clients with mobility challenges and embed culturally safe practices.

2. Music & Sound System Requirements:

- Music systems should support playlists grounded in international protocols (e.g., MAPS MDMA protocol).

- Music should:
 - Be primarily instrumental or minimally lyrical, avoiding potentially triggering content unless culturally specific music is requested.
 - Follow a therapeutic arc (calm entry, emotional expansion, integrative closure) that supports each phase of the psychedelic experience (MAPS, 2021; Barrett et al., 2018).
- High-fidelity speakers or clinical-grade headphones are essential for immersive quality, enhancing emotional depth and psychological safety (Kaelen et al., 2018).
- Individual preferences and silence must be respected throughout the session.

3. Emergency & Risk Management

- **Rescue Medication Protocols:**

Emergency response protocols must include pre-prescribed rescue medications such as:

- Oral benzodiazepines with rapid onset (e.g., diazepam)
- Antihypertensives (e.g., clonidine)
- Antiemetics (e.g., ondansetron)
- Neuroleptic medications (e.g., quetiapine, olanzapine) where clinically appropriate

Rescue medication selection should be individualised to participant needs and clinical context.

- **Medical Staffing:**

A medical doctor trained in PAP should be available to administer rescue medications where required. Alternatively, a registered nurse may administer under direct or telephonic medical direction, in accordance with jurisdictional requirements.

- **Crisis Plan & Escalation Flowchart:**

Each site must maintain a written, individualised medical and psychological crisis plan or flowchart for every participant. This must include:

- Steps to trigger emergency, paramedical, or crisis services
- Identification of available medical, paramedical, and nursing staff
- Local information on emergency response times and pathways

- **Vital Signs Monitoring:**

Monitoring of vital signs (e.g., heart rate, blood pressure, oxygen saturation) is required during dosing sessions.

4. Schedule 8 Medicine Handling:

- Secure storage for Schedule 8 (S8) substances must be maintained in accordance with state/territory regulations.
- Authorised staff to handle S8 medicines may include:
 - Medical practitioners
 - Nurse practitioners
 - Registered nurses (under appropriate order)
 - Endorsed enrolled nurses (under supervision, in some jurisdictions)
 - Authorised paramedics (for specified substances, under standing orders where permitted)

5. Data Collection & Quality Assurance:

- Sites must maintain secure data systems for tracking patient outcomes and adverse events.
- Six-monthly safety and outcome reports should be submitted to the TGA and/or relevant state or territory health authorities.
- Participation in a national registry is encouraged to support real-world safety and efficacy monitoring.

6. Equity & Cultural Safety:

- Aboriginal and Torres Strait Islander Clients: Facilities should enable the inclusion of cultural artefacts, support persons, and Indigenous health practitioners when requested. Culturally safe clinical pathways must be available.
- Regional and Rural Clients: Facilities should expand to include accredited outpatient clinics and rural health hubs that meet equivalent safety and governance standards to metropolitan sites, reducing travel burdens and improving access equity.
- Consumer Engagement: Site design and service delivery models should include consumer and carer input, especially from culturally diverse and geographically dispersed communities.

Delivering PAP in community and regional outpatient sites with robust governance, high-quality therapy rooms, evidence-informed music that respects individual cultural context, professional sound systems, vital signs monitoring, expanded rescue medication options, and an individualised crisis plan helps to ensure more equitable, safe, and ethically sound access.

5. Recommendations

In light of the demonstrated need for inclusive, scalable, and ethically grounded models of psychedelic-assisted psychotherapy (PAP), the Australian Multidisciplinary Association for Psychedelic Practitioners (AMAPP) submits the following policy amendments for consideration by the Therapeutic Goods Administration (TGA). These proposals are designed to enhance access, strengthen clinical safety, and align the regulatory framework with both international best practices and Australia's unique cultural landscape.

5.1 Broaden Recognition

First and foremost, AMAPP urges the TGA to formally broaden its recognition of eligible co-facilitators within psychedelic-assisted psychotherapy. The current implied limitation to psychiatrists and clinical psychologists, while well-intentioned from a risk management perspective, fails to account for the wide array of competent and appropriately trained professionals already delivering PAP in research and clinical settings. AMAPP proposes that the TGA acknowledge a multidisciplinary roster of co-facilitators, including but not limited to accredited psychiatrists, psychologists, psychotherapists, registered counsellors, social workers, registered nurses, paramedics, and general practitioners. Furthermore, AMAPP hopes for an extension of inclusion to Indigenous health practitioners with relevant therapeutic and psychedelic-specific training. This expansion acknowledges the real-world diversity of effective therapy dyads and recognises that competence, not profession alone, is the most appropriate basis for inclusion.

5.2 Clinical Governance

Second, AMAPP emphasises the need for a clinical governance model that maintains rigorous safety standards while allowing for workforce flexibility. All psychedelic-assisted psychotherapy services should operate under the supervision of an AHPRA-registered lead clinician, such as a psychiatrist or medical practitioner with appropriate PAP training. This lead clinician would be responsible for overall clinical oversight, including

pharmacovigilance and crisis response, while working in collaboration with co-facilitators to ensure therapeutic integrity across all phases of care. Accreditation and credentialing should be overseen by bodies such as AMAPP, which maintain clearly defined training requirements, role delineation, supervision structures, and codes of conduct. Practitioners should also be required to participate in continuous professional development, ongoing reflective practice, and structured peer supervision to ensure quality assurance and ethical alignment.

5.3 National Guidelines

Finally, AMAPP calls on the TGA to co-develop a set of national guidelines in partnership with credentialing bodies such as AMAPP. These guidelines should establish clear definitions of clinical roles, delineate minimum training standards, and outline the ethical and procedural boundaries within which PAP should occur. Such guidelines would not only provide clarity to prescribers and facilitators but also serve as a benchmark for evaluating new training programs and emerging models of care. Co-development would ensure that national guidelines are informed by real-world clinical practice, diverse stakeholder perspectives, and the growing body of international evidence. By adopting these amendments, the TGA would take a crucial step toward a regulatory framework that is inclusive, accountable, and fit for purpose in the evolving field of psychedelic-assisted psychotherapy.

5.4 Adopt AMAPP Credentialing Model

AMAPP proposes a comprehensive national framework for psychedelic-assisted psychotherapy that integrates clinical safety, practitioner suitability, ethical sensitivity, cultural competency, and workforce scalability. AMAPP recommends that the TGA formally endorse the AMAPP credentialing and supervision model as the minimum standard for the delivery of psychedelic-assisted psychotherapy in Australia. This model reflects both the complexity of the therapeutic modality and Australia's diverse clinical context, while offering a clear and actionable structure for training, accountability, and clinical governance. At the core of this framework is a tiered accreditation system that defines three distinct practitioner roles. The first is the Psychedelic Prescriber: a psychiatrist or medical doctor with Authorised Prescriber status and PAP-specific training, responsible for prescribing and pharmacovigilance. The second is the Psychedelic-Assisted Psychotherapist: a clinician with a background in psychotherapy, counselling, or social work who is trained to provide preparation, dosing support, and integration. The third role is the Psychedelic Facilitator: a co-therapist with PAP-specific training who may come from a broader range of health or

spiritual care professions, and who works under clinical supervision during the dosing and integration process. Each of these roles is governed by clearly defined training and supervision requirements. All accredited practitioners must complete a minimum of 100 hours of didactic training and 40 hours of experiential practice, including supervised dosing sessions. Full accreditation also requires active participation in regular supervision, professional development, and personal therapeutic work. These standards are aligned with international models such as those developed by MAPS and Fluence (2024) but are tailored specifically to the Australian healthcare and cultural context.

The AMAPP framework also specifies approved dyadic configurations for clinical delivery. Every psychedelic dosing session must be facilitated by a trained therapy dyad, comprising at least one Psychedelic-Assisted Psychotherapist and either another Therapist or a Facilitator. Both members of this dyad must be registered with a national professional body such as AHPRA, PACFA, ACA, or equivalent. This model ensures appropriate clinical oversight while allowing flexibility to match client needs with practitioner competencies. Critically, the AMAPP framework embeds ethical and cultural inclusion as foundational principles and supports accreditation pathways for Indigenous clinicians and other professionals who are suitably qualified and registered with appropriate peak bodies such as PACFA. It also prioritises client safety and therapeutic integrity through strict codes of conduct and ethical review processes. Endorsing the AMAPP model as the national standard for psychedelic-assisted psychotherapy will establish a clear evidence-based framework for safe and inclusive care. It will support the expansion of a qualified, culturally competent workforce and provide the clinical and ethical infrastructure necessary to meet growing public and medical interest in this emerging field.

5.5 Co-Develop National PAP Guidelines

To ensure the integrity, safety, and establishment of psychedelic-assisted psychotherapy as a treatment intervention in Australia, AMAPP calls for a formal partnership between the Therapeutic Goods Administration (TGA), the Psychotherapy and Counselling Federation of Australia (PACFA), The Royal Australian and New Zealand College of Psychiatrists RANZCP, the Australian Association of Psychology Inc. (AAPI), Human Research Ethics Committees (HRECs), and other relevant stakeholders. This partnership would provide the foundation for a coherent, clinically robust, and ethically attuned framework for psychedelic psychotherapy as it transitions from clinical trials to broader therapeutic use. A first priority

within this collaboration is the co-development of clear and enforceable scope of practice definitions. These definitions must reflect the distinct roles of psychedelic prescribers, psychotherapists, and facilitators, as outlined by AMAPP's model. These definitions should delineate the boundaries of clinical responsibility, therapeutic function, and interdisciplinary coordination ensuring that practitioners operate within the limits of their training and accreditation. This approach moves beyond professional title as a proxy for competency and instead recognises the diversity of skills required to safely deliver care within a PAP context. This clarity would improve client outcomes, support practitioners, and support organisations working within this emerging space.

Alongside scope of practice definitions, the partnership should develop national governance and audit structures to ensure clinical accountability. This includes the implementation of protocols for case review, adverse event reporting, clinical documentation, and ethical oversight. These standards of practice could best create a responsive, learning-oriented governance environment that centres on safety, quality, and practitioner development. HRECs, with their experience in overseeing clinical research, can play a critical role in shaping these governance mechanisms as psychedelic psychotherapy begins to grow. Finally, the partnership must embed cultural and trauma-informed care protocols at the heart of all regulatory and clinical frameworks. Psychedelic-assisted psychotherapy frequently activates deep psychological and existential material. The PAP process may involve revisiting complex trauma, dislocation, or spiritual emergence which necessitates a high degree of therapeutic attunement and cultural literacy. National protocols must therefore incorporate trauma-informed principles—such as safety, agency, and emotional regulation. In building these foundations collaboratively the TGA, AAPI AMAPP, PACFA, and HRECs can develop a nationally consistent and internationally respected model for psychedelic-assisted care—one that is not only clinically effective but ethically coherent, culturally accountable, and grounded in therapeutic best practice.

AMAPP recognises that these recommendations do not represent the full scope of work required to amend the current TGA frameworks. Rather, they signal the need for a broader program of collaborative work involving the TGA, HRECs, peak professional registration bodies, AMAPP, and other key stakeholders. This work is essential to ensure clarity, standardised practice, and the highest standards of safety, integrity, and professional

accountability. AMAPP is committed to actively contributing to and supporting the development and implementation of the additional measures required.

To reiterate, this submission identifies and justifies the need for change, while also acknowledging the further work necessary to realise it.

6. Conclusion

Australia possesses a rigorous research environment, highly trained clinicians, established educational frameworks, and an increasingly engaged public, which positions the country to play a leading role in shaping the future of psychedelic-assisted psychotherapy internationally. Yet the potential for Australia to lead in this field is at risk of being undermined by a narrow and exclusionary implementation of the current policy. This policy has the potential to exclude some of Australia's internationally recognised leading experts and clinicians. The current absence of formal recognition for psychotherapists and other qualified professionals may create an unintended misalignment with both clinical practice and international precedent. This omission is not rooted in concerns over safety or clinical risk but instead reflects an outdated and overly restrictive conception of professional identity that is incompatible with the emerging needs and realities of the field.

Psychotherapists, counsellors, social workers, nurses, and paramedics already play a central role in the therapeutic delivery of psychedelic care, both in Australia and internationally. Many of these professionals are not only experienced in trauma-informed, relational, and depth psychotherapeutic work, but also serve as trainers, supervisors, and lead clinicians within psychedelic research and practice settings. Their exclusion from formal recognition within the current policy effectively disqualifies some of the most clinically competent and ethically grounded practitioners in the country.

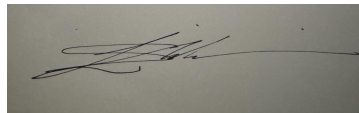
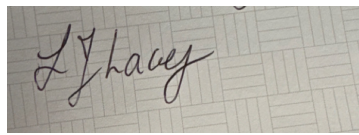
Correcting this regulatory oversight is essential if Australia is to develop a safe, ethical, and scalable psychedelic psychotherapy workforce. Recognising trained psychotherapists and allied health professionals will directly expand access to care, particularly in regional and underserved areas. It will also allow for the development of a workforce that is not only larger, but more appropriately trained for the relational and process-oriented demands of psychedelic-assisted psychotherapy. AMAPP urges the Therapeutic Goods Administration to revise its implementation of current policy to include a broader range of appropriately

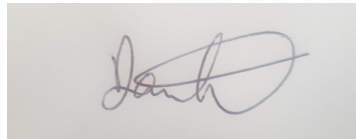
credentialed practitioners. AMAPP offers our credentialing and supervision standards as a resource for national adoption. These standards are grounded in evidence, developed in consultation with senior clinicians and educators, and explicitly designed to uphold clinical safety, ethical responsibility, and cultural inclusion. AMAPP remains committed to working in partnership with the TGA, HRECs, and other stakeholders to ensure that Australia's regulatory framework reflects the best available knowledge and serves the full diversity of those who stand to benefit from psychedelic-assisted psychotherapy.

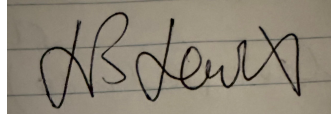
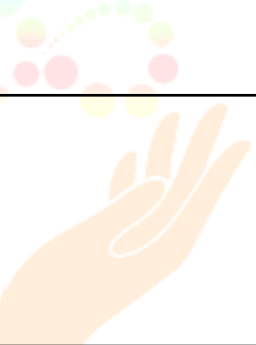
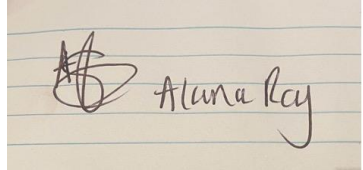
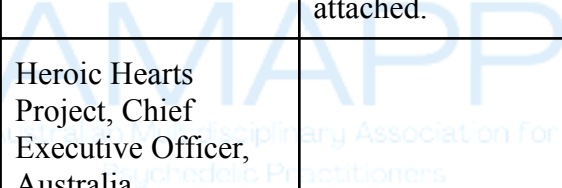
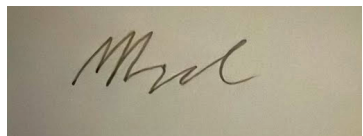
6.1 Endorsements

PACFA has provided endorsement for this submission. Please refer to [PACFA's Endorsement Letter](#) for specific conditions.

The following signatures represent the formal endorsement of this submission by the undersigned individuals and/or organisations. Each has reviewed the contents of this document and supports the recommendations and positions outlined.

Name	Profession	Comments	Date/ Signature
Lana Sciberras	Clinical Psychotherapist PAT trial therapist		 28.7.2025
Ludo Kourouvanis	Social worker / therapist		28.07.2025 E(Ludo)Kourouvanis
Lauren Lacey	Psychotherapist		28.07.2025 
Melissa Warner	Student psychologist and psychedelic researcher		28/7/2025 
Ella Shannon Morter	Psychotherapist / Counsellor and Clinical Sexologist		29/7/2025

			
Dr David Graham	Psychiatrist and Psychotherapist	Medical Director GoodMind Therapeutics	29 July 2025
Dr Nikola Ognjenovits	Addiction Medicine Specialist Physician Psychotherapist Psychedelic Therapist in private practice		29 July 2025
Helen Sheeran	Accredited Mental Health Social Worker & Psychotherapist		29.07.2025
Ashley White	Counselling Psychologist	Working as psychedelic-assisted therapist in clinical practice	29/07/2025
Dafna Kronental	Psychotherapist & Educator of counselling and psychotherapy		29/7/2025 
Tara Green	Clinical Psychotherapist	Psychotherapist for Monash PAP Research trials.	30/7/25 
Adam Grosman	Counselling & Body Psychotherapy Student, Researcher & Community Member	Lab Volunteer for Swinburne Clinical Trials & Community leader for Australian Psychedelic Society	31/7/25 
Dr Jennifer Long	Psychiatrist and Psychotherapist	GoodMind Therapeutics	31/8/25 

Dr Llewellyn Lewis	Psychiatrist, PI EMPACT study	Medical Director Rainbow-Mandala Clinic	1/8/2025 
Melissa Errey	Accredited Exercise Physiologist	ADF Rehab Consultant, PAT advocate, working toward an expanded AEP Scope of Practice in preparation for acceptance of body-based health practitioners having a role in PAP.	04/08/2025 
Dr Israel Berger	Senior Psychiatry Registrar		4/8/25
Dr Lani Roy	AMAPP chair, Psychologist, Social Worker, Psychedelic Therapist, Supervisor and Researcher.		7/7/2025 
Johanna De Wever	PACFA Chief Executive Officer	Refer to the endorsement letter attached.	7/7/2025A
Michael Raymond	Heroic Hearts Project, Chief Executive Officer, Australia		
Tobias Penno	Acedemic / Lecturer in Social Work at University of Western Australia Private Practice Psychotherapist	Practicing Psychedelic-Assiste d Therapist in Clinical Trial and Community Clinic settings	

References

- ACA. (2023). *Scope of practice for counsellors* [PDF]. Australian Counselling Association. <https://www.theaca.net.au>
- AHPRA. (2023). *Annual report 2022–2023*. Australian Health Practitioner Regulation Agency. <https://www.ahpra.gov.au/Publications/Annual-reports.aspx>
- AMAPP. (2025). *Accreditation guidelines* [PDF]. Australian Multidisciplinary Association for Psychedelic Practitioners. <https://amapp.org.au>
- AMAPP. (2024). *Supervision guidelines* [PDF]. Australian Multidisciplinary Association for Psychedelic Practitioners. <https://amapp.org.au>
- APAC. (2019). *Accreditation standards for psychology programs*. Australian Psychology Accreditation Council.
- Australian Health Ministers' Advisory Council. (2020). *Guidelines for the regulatory assessment of health professions*. Commonwealth of Australia.
- Australian Institute of Health and Welfare. (2022). *Mental health services in Australia*. <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia>
- Barrett, F. S., Robbins, H., Smooke, D., Brown, J. L., & Griffiths, R. R. (2018). Psychedelics and music: Neuroscience and therapeutic implications. *International Review of Psychiatry*, 30(4), 350–362. <https://doi.org/10.1080/09540261.2018.1484342>
- BrainFutures. (2023). *Professional practice guidelines for psychedelic-assisted psychotherapy*. <https://www.brainfutures.org>
- California Institute of Integral Studies. (2023). Certificate in psychedelic-assisted therapies and research. <https://www.ciis.edu>
- Canadian Psychedelic Association. (2025). Certification programs in psychedelic-assisted therapy. <https://psychedelicassociation.net>
- Centre for Psychedelic-Assisted Therapies. (2023). Professional training overview. <https://www.monash.edu/medicine/psychedelic-therapies>
- College of Physicians & Surgeons of Alberta. (2023). Psychedelic-assisted psychotherapy accreditation standards (draft). <https://cpsa.ca/facilities-clinics/accreditation/psychedelic-assisted-psychotherapy>
- Dudgeon, P., Milroy, H., & Walker, R. (Eds.). (2014). *Working together: Aboriginal and Torres Strait Islander mental health and wellbeing principles and practice*. Australian Government Department of the Prime Minister and Cabinet.

- Flavel J, Kedzior SG, Isaac V, Cameron D, Baum F (2024). Regional health inequalities in Australia and social determinants of health: analysis of trends and distribution by remoteness. *Rural and Remote Health*, 24, Article 7726.
<https://doi.org/10.22605/RRH7726>
- Fluence. (2024). *Training program overview and mission statement*.
<https://fluencetraining.com>
- Gorman, I., Nielson, E., Molinar, A., Cassidy, K., & Sabbagh, J. (2021). Psychedelic harm reduction and integration: A transtheoretical model for clinical practice. *Frontiers in Psychology*, 12, Article 645246. <https://doi.org/10.3389/fpsyg.2021.645246>
- Health Canada. (2023). Special access program notice for psychedelic assisted psychotherapy.
<https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs/psychedelic-assisted-psychotherapy.html>
- Horvath, A. O., & Bedi, R. P. (2002). The alliance. In J.C. Norcross (Ed.), *Psychotherapy relationships that work*. New York: Oxford University Press.
- Inwardbound Institute. (2025). Psychedelic assisted therapy education programme.
<https://inwardbound.nl/services/psychedelic-therapy-training>
- Johns Hopkins University. (2018). Psychedelic research program therapy room guidelines. Center for Psychedelic and Consciousness Research.
- Kaelen, M., Giribaldi, B., Raine, J., Evans, L., Timmerman, C., Rodriguez, N., Roseman, L., Feilding, A., Nutt, D. J., & Carhart-Harris, R. L. (2018). The hidden therapist: Evidence for a central role of music in psychedelic therapy. *Psychopharmacology*, 235(2), 505–519. <https://doi.org/10.1007/s00213-017-4820-5>
- Kavanagh, B.E., Corney, K.B., Beks, H. et. al. (2023). A scoping review of the barriers and facilitators to accessing and utilising mental health services across regional, rural, and remote Australia. *BMC Health Services Research*, 23, Article 1060.
<https://doi.org/10.1186/s12913-023-10034-4>
- MAPS. (2021). *MDMA-assisted therapy training manual*. Multidisciplinary Association for Psychedelic Studies.
- MAPS Israel. (n.d.). *MAPS Israel: MDMA-assisted therapy for PTSD and treatment-resistant populations*. <https://www.maps-israel.org>
- MAPS Public Benefit Corporation. (2021). *Code of ethics for psychedelic psychotherapy* (Version 4). <https://cdn.mapspublicbenefit.com>

- MAPS. (2022). MAPS MDMA therapy training program. <https://maps.org/training>
- MAPS Public Benefit Corporation. (2023). *MDMA-assisted therapy for PTSD: Overview of MAPS-sponsored Phase 3 trials*. Multidisciplinary Association for Psychedelic Studies. <https://maps.org/2023/01/05/prior-positive-results-confirmed/>
- Mithoefer, M. (2017). *A manual for MDMA-assisted psychotherapy in the treatment of PTSD* (Version 8). Multidisciplinary Association for Psychedelic Studies.
- NASRHP. (2020). *Membership standards*. National Alliance of Self-Regulating Health Professions.
- National Rural Health Alliance (2021). Fact Sheet: Mental Health in Rural and Remote Australia. Available at: [nrha-mental-health-factsheet-july2021.pdf](#) Accessed 3 August, 2025
- Oregon Health Authority. (2023). Oregon Psilocybin Services training program & Facilitator licensure standards. <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Training-Program-Approval.aspx>
- PACFA. (2021a). Indigenous Healing Practice Training Standards [PDF]. PACFA/CATSIHP.
- PACFA. (2021b). Indigenous Healing Practice Training Standards: 8 key features of Indigenous Healing Practice [Figure]. PACFA/CATSIHP.
- PACFA. (2022a). *Annual report 2022–2023: Ethics and complaints*. Psychotherapy and Counselling Federation of Australia. <https://pacfa.org.au>
- PACFA. (2022b). PACFA training standards. Melbourne, VIC: PACFA. <https://pacfa.org.au/common/Uploaded%20files/Psychotherapy-Training-Standards-2020.pdf>
- PACFA. (2025). Professional competencies for registration as a certified practising counsellor. Melbourne, VIC: PACFA. <https://pacfa.org.au/portal/portal/Training-and-Careers/Accreditation/Accreditation-Standards-Review.aspx>
- Páleníček, T., Vejmla, Č., & Páleníček, T. (2022). The PSIKET clinical trial: Comparing the antidepressant effects of psilocybin versus ketamine at the Czech National Institute of Mental Health. *Frontiers in Psychiatry*, 13, Article 1024. <https://doi.org/10.3389/fpsy.2022.01024>
- RANZCP. (2025). Communities in Rural Australia. Available at: <https://www.ranzcp.org/college-committees/key-areas-of-focus/rural->

psychiatry/about-rural-psychiatry/communities-in-rural-australia

Accessed, 3rd August 2025

- Schwartz, B., Hehlmann, M. I., Deisenhofer, A.-K., Rubel, J. A., Fischer, L., Lutz, W., & Schöttke, H. (2025). Elucidating therapist differences: Therapists' interpersonal skills and their effect on treatment outcome. *Behaviour Research and Therapy*, 186, 104689. <https://doi.org/10.1016/j.brat.2025.104689>
- Tai, S. J., Nielson, E. M., Lennard-Jones, M., Johanna Ajantaival, R. L., Winzer, R., Richards, W. A., ... & Malievskaia, E. (2021). Development and evaluation of a therapist training program for psilocybin therapy for treatment-resistant depression in clinical research. *Frontiers in psychiatry*, 12, 586682.
- The Australian. (2023, September 12). Inside the secretive but growing world of MDMA-led therapy. *The Australian*.
<https://www.theaustralian.com.au/health/mental-health/inside-the-secretive-but-growing-world-of-mdmaled-therapy/news-story/3cf3f52f12d3c9c2d52b048785b1453c>
- TGA. (2023). Authorised Prescriber scheme: MDMA and psilocybin guidance.
<https://www.tga.gov.au>
- Tschuschke, V., Koemeda-Lutz, M., von Wyl, A., Cramer, A., & Schulthess, P. (2020). The impact of patients' and therapists' views of the therapeutic alliance on treatment outcome in psychotherapy. *Journal of Nervous and Mental Disease*, 208(1), 56–64.
<https://doi.org/10.1097/NMD.0000000000001111>
- Wampold, B.E., & Imel, Z.E. (2015). *The Great Psychotherapy Debate: The Evidence for What Makes Psychotherapy Work* (2nd ed.). Routledge.
<https://doi.org/10.4324/9780203582015>
- Watts, R., Day, C., Krzanowski, J., Nutt, D., & Carhart-Harris, R. L. (2017). Patients' accounts of increased “connectedness” and “acceptance” after psilocybin for treatment-resistant depression. *Journal of Humanistic Psychology*, 57(5), 520–564.
<https://doi.org/10.1177/0022167817709585>

Appendix A: Table of Health, Mental Health & Social Care Professions

Profession	Peak Body / Association	Registration Type	Scope of Practice (One-Line)
General Practitioner (GP)	AHPRA (Medical Board of Australia), RACGP	Mandatory (AHPRA)	Primary medical care, diagnosis, treatment, referrals.
Psychiatrist	AHPRA (Medical Board), RANZCP	Mandatory (AHPRA)	Specialist mental health physician, medication, psychotherapy, complex case management.
Registered Nurse (RN)	AHPRA (Nursing & Midwifery Board), ACN	Mandatory (AHPRA)	Nursing care, clinical assessment, health education, care coordination.
Mental Health Nurse	AHPRA (Nursing & Midwifery Board), ACMHN	Mandatory (AHPRA)	Specialist mental health care, recovery-oriented practice, case management.
Paramedic	AHPRA (Paramedicine Board), Paramedics Australasia	Mandatory (AHPRA)	Emergency response, acute medical care, transport to hospital.
Psychologist (General)	AHPRA (Psychology Board), APS	Mandatory (AHPRA)	Psychological assessment, therapy, behaviour change interventions.

Psychologist (Clinical)	AHPRA (Psychology Board), APS	Mandatory (AHPRA)	Specialist psychological assessment and treatment of complex mental health conditions.
Occupational Therapist (OT)	AHPRA (Occupational Therapy Board), OTA	Mandatory (AHPRA)	Functional rehabilitation, disability support, life skill training.
Mental Health OT	AHPRA (OT Board), OTA (credentialed)	Mandatory (AHPRA)	Mental health functional support, sensory modulation, recovery support.
Aboriginal Health Practitioner	AHPRA (ATSI Health Practice Board)	Mandatory (AHPRA)	Culturally safe primary healthcare, health promotion, liaison.
Social Worker	AASW (Australian Association of Social Workers)	Voluntary (self-regulated)	Social support, advocacy, mental health case work, welfare.
Mental Health Social Worker	AASW (MH endorsement)	Voluntary (self-regulated)	Specialist therapy, mental health assessments, Medicare-rebated counselling.
Clinical Counsellor*	PACFA (Registered Clinical Counsellor credential)	Voluntary (self-regulated)	Advanced counselling with 750+ client hours and university-level qualification.

Clinical Psychotherapist *	PACFA (Registered Clinical Psychotherapist credential)	Voluntary (self-regulated)	Depth psychotherapy; advanced credential including personal therapy & specialist training.
Counsellor (ACA Level 3 & 4)	ACA (Australian Counselling Association)	Voluntary (self-regulated)	General counselling, support, short-term interventions.
Art Therapist	ANZACATA	Voluntary (self-regulated)	Creative arts-based therapy for emotional and psychological wellbeing.
Music Therapist	AMTA	Voluntary (self-regulated)	Music-based interventions for emotional and physical health.

Footnotes

- **Protected titles:** Professions regulated by **AHPRA** (General Practitioner, Psychiatrist, Nurse, Paramedic, Psychologist, Occupational Therapist, Physiotherapist, Pharmacist, Aboriginal Health Practitioner).
- **Self-regulated:** *Clinical Counsellor* and *Clinical Psychotherapist* are **not protected titles**; they are **voluntary credentials** managed by PACFA to recognise advanced training and experience.
- **Voluntary professions:** Counsellors and art/music therapists, rely on association membership and employer governance.

Appendix B: Counsellor & Psychotherapy Registration (PACFA and ACA) and Practitioner Readiness for Psychedelic-Assisted Psychotherapy (PAP)

1. Professional Role Definitions

- **Counsellor**

A professional trained in counselling theory and techniques, typically at diploma or bachelor's level. Counsellors primarily focus on supportive counselling, wellbeing promotion, and early intervention services.

- **Psychotherapist**

A practitioner delivering longer-term, depth-oriented therapy often using advanced relational and experiential techniques. In Australia, “psychotherapist” is a self-regulated title and is not legally protected.

- **Registered Clinical Counsellor**

A PACFA-recognised counsellor with postgraduate qualifications, a minimum of 750 client contact hours, and 75 hours of clinical supervision, meeting higher clinical practice standards.

- **Registered Clinical Psychotherapist**

A PACFA-recognised psychotherapist who has completed advanced psychotherapy training (≥ 450 hours specialist content), personal therapy, supervised practice, and meets ongoing CPD and supervision requirements.

2. Regulatory Context

Counselling and psychotherapy are **self-regulated professions** in Australia.

- **Psychologists and psychiatrists** are regulated by the Australian Health Practitioner Regulation Agency (AHPRA).
- **Counsellors and psychotherapists** gain professional recognition through peak bodies:
 - **PACFA** – Psychotherapy and Counselling Federation of Australia
 - **ACA** – Australian Counselling Association

3. PACFA Membership, Governance & Professional Standards

Recognition and Governance

- Allied Health Recognition – PACFA is a full member of Allied Health Professions Australia (AHPA) and a qualifying member of the National Alliance of Self-Regulating Health Professions (NASRHP, 2020; PACFA, 2024a).
- Governance Framework – PACFA standards include:
 - Code of Ethics and Professional Conduct
 - CPD: ≥ 20 hours annually
 - Clinical supervision: ≥ 10 hours annually
 - Annual audit of $\sim 5.5\%$ of registrants
 - Public grievance process with transparent outcomes (PACFA, 2024b)
 - Registration standards (PACFA, n.d.)
 - Scope of practice (PACFA, 2018)

Membership Categories

- **Student Member** – Enrolled in approved counselling/psychotherapy training (non-clinical)
- **Affiliate Member** – Non-practising membership
- **Provisional Clinical Member** – Postgraduate qualified but completing supervised client hours
- **Clinical Registered Psychotherapist/Counsellor** – Full practising recognition as Counsellor or Psychotherapist (≥ 750 client hours and ≥ 75 supervision hours post-qualification)
- **Clinical Psychotherapist (College of Psychotherapy)** – Clinical members with ≥ 450 hours specialist psychotherapy training and personal therapy

4. ACA Membership Scope and Standards

Scope

ACA is the largest counselling association in Australia, focusing on general counselling and wellbeing services. ACA does not differentiate counsellors from psychotherapists and is **not** a NASRHP member (ACA, 2023a).

Membership Levels

- **Level 3** – Bachelor/Master of Counselling (AQF 7–9) with < 750 client contact hours
- **Level 4** – Bachelor/Master of Counselling (AQF 7–9) with ≥ 750 client contact hours and ≥ 75 supervision hours (ACA, 2023b)

Use of Titles

ACA members may use the title “psychotherapist”; however, ACA does not require specialised psychotherapy training to adopt this title.

5. Comparison: PACFA vs ACA Pathways

Category	PACFA (NASRHP Member)	ACA
Student	Enrolled in approved training (non-clinical)	Student/associate membership
Affiliate	Non-practising membership option	Not available
Provisional Clinical	Postgraduate qualified, working toward recognition	Level 3 (< 750 client hours)
Clinical	≥ 750 client hours & ≥ 75 supervision hours	Level 4 (≥ 750 client hours & ≥ 75 supervision)
Clinical Psychotherapist	≥ 450 hours psychotherapy training + personal therapy	No separate category; “psychotherapist” title allowed

Governance	CPD 20 hours, supervision 10 hours, 5.5 % annual audit, public grievance process	CPD 25 points, supervision encouraged (not annually audited)
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6. Why PAP Is an Advanced Scope of Practice

Psychedelic-assisted psychotherapy (PAP) involves:

- Non-ordinary states of consciousness
- Trauma activation and dissociation
- Spiritual emergence and existential crises
- Complex transference and counter-transference

These dimensions require advanced competencies in:

- Relational depth work
 - Trauma-informed care and risk management
 - Integration of symbolic, spiritual, and existential content
- (Mithoefer et al., 2016; Phelps, 2017; Watts & Luoma, 2020)

7. Practitioner Readiness for PAP

PACFA Clinical Members (especially psychotherapists) are better equipped because:

- **Advanced Psychotherapy Training** – Specialist, depth-oriented, trauma-focused, relational, and altered-state competencies.

ACA Members (Level 3–4) – Skilled in general counselling but not required to complete depth-oriented psychotherapy or altered-state competencies unless they pursue additional postgraduate psychotherapy pathways.

8. Recommended Workforce Development Pathway for PAP

- **Postgraduate Training** – Encourage ACA Level 3–4 counsellors to complete AQF 8+ psychotherapy or clinical counselling programs.

- **Specialist PAP Training** – Accredited trauma-informed, somatic, transpersonal therapy, and psychedelic integration programs (Phelps, 2017).
- **Supervised Clinical Hours** – PAP-specific supervised practice.
- **Professional Registration Upgrade** – Attain PACFA Clinical or Clinical Psychotherapist status.
- **Annual CPD & Supervision** – Ongoing professional development in trauma, ethics, risk, and cultural safety.

Appendix B: References

- ACA. (2023a). *Membership levels and requirements*. Australian Counselling Association,. <https://www.theaca.net.au>
- ACA. (2023b). *Scope of practice for counsellors* [PDF]. Australian Counselling Association. <https://www.theaca.net.au>
- PACFA. (2018). *PACFA scope of practice for Registered Counsellors* [PDF]. Psychotherapy and Counselling Federation of Australia. <https://www.pacfa.org.au/common/Uploaded%20files/PCFA/Documents/Documents%20and%20Forms/Scope-of-Practice-for-Registered-Counsellors-2018.pdf>
- PACFA. (2024a). *AHPA membership announcement*. Psychotherapy and Counselling Federation of Australia. <https://www.pacfa.org.au>
- PACFA. (2024b). *NASRHP qualifying membership*. Psychotherapy and Counselling Federation of Australia. <https://www.pacfa.org.au>
- PACFA. (n.d.). *Registration Standards & Associated Registration Standards*. Psychotherapy and Counselling Federation of Australia. <https://pacfa.org.au/portal/Membership/Member-Requirements/Portal/Membership/Member-Requirements.aspx?>
- Phelps, J. (2017). Developing guidelines and competencies for the training of psychedelic therapists. *Journal of Humanistic Psychology*, 57(5), 450–487. <https://doi.org/10.1177/0022167817711304>
- Mithoefer, M. C., Wagner, M. T., Mithoefer, A. T., Jerome, L., & Doblin, R. (2016). The safety and efficacy of $\pm$ 3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD. *Journal of Psychopharmacology*, 25(4), 439–452. <https://doi.org/10.1177/0269881110378371>

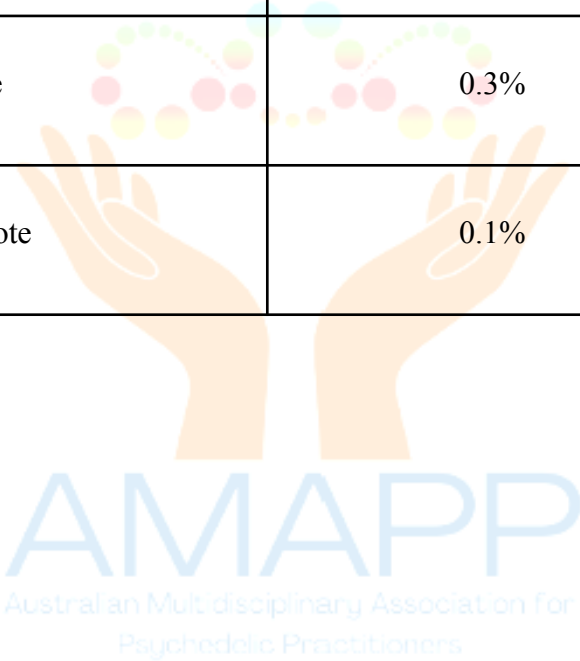
NASRHP. (2020). *Membership standards*. National Alliance of Self-Regulating Health Professions.

Watts, R., & Luoma, J. B. (2020). The use of psychological flexibility in psychedelic research and therapy. *Frontiers in Psychology*, *11*, 2196.
<https://doi.org/10.3389/fpsyg.2020.02196>



Appendix C: AIHW data

Region	% of Psychologists
Major cities	82.9%
Inner regional	12.4%
Outer regional	4.2%
Remote	0.3%
Very remote	0.1%



Appendix D: Psychedelic Clinical Trial Therapist Configurations

Trial Date / Status	Medicine	Therapist Configuration	Training Requirements	Team Composition Summary	Ref
Fully Enrolled	MDMA	Co-facilitator teams approved by sponsor (MAPS)	MAPS training	Unspecified professions, MAPS certification	[1]
Not yet recruiting	MDMA	Two-person: medicine prescriber + licensed psychotherapist	MAPS MT2 protocol training	Physician, licensed psychotherapist/trainee	[2]
Enrolling	MDMA	Two MAPS-trained therapists (PTSD experience preferred)	MAPS manual training	Licensed therapists (psychology/social work)	[3]
Enrolling (IUSA5)	MDMA	Two MAPS-trained therapists (PTSD experience preferred)	MAPS manual training	Licensed therapists (psychology/social work)	[4]
Start-up (INZL1)	MDMA	Two MAPS-trained therapists (PTSD experience preferred)	MAPS manual training	Licensed therapists (psychology/social work)	[5]
2018	MDMA	Team (unspecified)	GCP, unspecified	Clinical researchers, therapists not specified	[6]

2011	MDMA	2–3 psychotherapists + emergency physician + consultant nurse	MAPS manual + Grof principles	Psychotherapists, physician, nurse	[7]
2021	MDMA	Two-person team (one licensed psychotherapist)	MAPS therapy training + supervision	Licensed psychotherapist + assistant	[8]
2019	MDMA	Male/female therapist team	MAPS training	Psychologists, counsellors, psychotherapists	[9]
2023	MDMA + LSD	Not specified	GCP	Likely mixed team	[10]
2022	Psilocybin	Lead + assistant (psychologists, psychiatrists, nurses)	Therapist training program	Psychologists, psychiatrists, nurses, CBT	[11]
2016	Psilocybin	Monitors (college grad to PhD)	Altered states experience training	Lay monitors to PhD psychologists	[12]
2014	LSD	Male/female co-therapist team + nurse	MAPS training	Psychiatrist/psych otherapist + nurse	[13]
2014	Psilocybin	2–3 staff including one PhD psychologist	Psilocybin study-specific training	PhD psychologist + research staff	[14]
2023	Psilocybin	Two psychiatrists present	GCP	Psychiatrists only	[15]

2023	Ketamine	Anaesthesiologist tech + psychiatrist + anaesthesiologist	Medical safety compliance	Anaesthesiologist, psychiatrist, technician	[16]
2023	Psilocybin	Lead (PhD/MD) + co-facilitators (bachelor mental health)	Usona facilitator training	Clinical/counselling psychologists, psychiatrists	[17]
Jan 2019 – Mar 2020	Psilocybin	One clinical psychologist/psychotherapist /psychiatrist + trainee	Not specified	Psychologist/psychiatrist + trainee	[18]
July 2019	Psilocybin	Two facilitators (social work, psychology, psychiatry)	Not specified	Social workers, psychologists, psychiatrists	[19]
All Other MAPS MDMA Trials	MDMA	Standard two-therapist team	MAPS manual training	Multidisciplinary therapists	[20]

Appendix D: References

1. MAPS. (2023). *A phase 1 placebo-controlled MDMA study*. Multidisciplinary Association for Psychedelic Studies (MAPS). <https://maps.org>
2. MAPS Public Benefit Corporation. (2019). *MT2 protocol amendment 2*. Multidisciplinary Association for Psychedelic Studies.
3. Australian New Zealand Clinical Trials Registry. (2019). *Australian MDMA-assisted PTSD study (PRISM)*. <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377613>
4. MAPS. (2020). *IUSA5 protocol*. Multidisciplinary Association for Psychedelic Studies.

5. MAPS. (2020). *INZLI protocol*. Multidisciplinary Association for Psychedelic Studies.
6. Danforth, A. L., Grob, C. S., Struble, C., Feduccia, A. A., Walker, N., Jerome, L., & Emerson, A. (2018). Reduction in social anxiety after MDMA-assisted psychotherapy with autistic adults: A randomized, double-blind, placebo-controlled pilot study. *Psychopharmacology*, 235(11), 3137–3148. <https://doi.org/10.1007/s00213-018-5010-9>
7. Mithoefer, M. C., Wagner, M. T., Mithoefer, A. T., Jerome, L., & Doblin, R. (2011). The safety and efficacy of $\pm$ 3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: The first randomized controlled pilot study. *Journal of Psychopharmacology*, 25(4), 439–452. <https://doi.org/10.1177/0269881110378371>
8. Mitchell, J. M., Bogenschutz, M., Lilienstein, A., Harrison, C., Kleiman, S., Parker-Guilbert, K., ... & Doblin, R. (2021). MDMA-assisted therapy for severe PTSD: A randomized, double-blind, placebo-controlled phase 3 study. *Nature Medicine*, 27, 1025–1033. <https://doi.org/10.1038/s41591-021-01336-3>
9. Mithoefer, M. C., Feduccia, A. A., Jerome, L., Wagner, M., Wymer, J., Emerson, A., ... & Doblin, R. (2019). MDMA-assisted psychotherapy for treatment of PTSD: Study design and rationale for phase 3 trials based on pooled analysis of six phase 2 randomized controlled trials. *Psychopharmacology*, 236, 2735–2745. <https://doi.org/10.1007/s00213-019-05249-5>
10. Straumann, I., Koek, R. J., Yazar-Klosinski, B., Emerson, A., Jerome, L., Feduccia, A. A., ... & Doblin, R. (2023). Extended safety follow-up of MDMA-assisted psychotherapy for PTSD. *Neuropsychopharmacology*. Advance online publication. <https://doi.org/10.1038/s41386-023-01609-0>
11. Goodwin, G. M., Aaronson, S. T., Alvarez, O., Arden, P. C., Baker, B. R., Bennett, J. C., ... & Chou, J. (2022). Rapid reduction in symptoms of depression with esketamine nasal spray: A double-blind, randomized, placebo-controlled study. *New England Journal of Medicine*, 387(18), 1637–1648. <https://doi.org/10.1056/NEJMoa2206443>
12. Griffiths, R. R., Johnson, M. W., Carducci, M. A., Umbricht, A., Richards, W. A., Richards, B. D., ... & Klinedinst, M. A. (2016). Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. *Journal of Psychopharmacology*, 30 (12), 1181–1197. <https://doi.org/10.1177/0269881116675513>

13. Gasser, P., Kirchner, K., & Passie, T. (2014). LSD-assisted psychotherapy for anxiety associated with a life-threatening disease: A qualitative study of acute and sustained subjective effects. *Journal of Nervous and Mental Disease*, 202 (7), 513–519.
<https://doi.org/10.1097/NMD.0000000000000113>
14. Johnson, M. W., Garcia-Romeu, A., Cosimano, M. P., & Griffiths, R. R. (2014). Pilot study of the 5-HT_{2A} receptor agonist psilocybin in the treatment of tobacco addiction. *Journal of Psychopharmacology*, 28 (11), 983–992.
<https://doi.org/10.1177/0269881114548296>
15. Wall, M. B., Turnbull, O., Hopkins, L., & Roseman, L. (2023). A qualitative exploration of therapeutic processes and outcomes of psilocybin-assisted therapy for depression. *Journal of Affective Disorders*, 333, 321–330.
<https://doi.org/10.1016/j.jad.2023.04.081>
16. Talaei, A., Shabahang, R., Khezri, Z., ... & Ghoreishi, F. S. (2023). Efficacy and safety of psilocybin in treatment-resistant depression: An Iranian perspective. *Iranian Journal of Psychiatry*, 18(4), 396–405.
17. Raison, C. L., Daly, E. J., Trivedi, M. H., Thase, M. E., Shelton, R. C., Asgharnejad, M., ... & Drevets, W. C. (2023). Efficacy and safety of zuranolone in major depressive disorder: A randomized clinical trial. *JAMA*, 330(9), 843–853.
<https://doi.org/10.1001/jama.2023.14530>
18. Carhart-Harris, R., Giribaldi, B., Watts, R., Baker-Jones, M., Murphy-Beiner, A., Murphy, R., ... & Nutt, D. J. (2021). Trial of psilocybin versus escitalopram for depression. *New England Journal of Medicine*, 384(15), 1402–1411.
<https://doi.org/10.1056/NEJMoa2032994>
19. Davis, A. K., Barrett, F. S., May, D. G., Cosimano, M. P., Sepeda, N. D., Johnson, M. W., & Griffiths, R. R. (2021). Effects of psilocybin-assisted therapy on major depressive disorder: A randomized clinical trial. *JAMA Psychiatry*, 78 (5), 481–489.
<https://doi.org/10.1001/jamapsychiatry.2020.3285>