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Critique of the Royal Australian and New Zealand College of Psychiatrists Psychedelic Therapy Clinical Memorandum, Dated May 2020

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ABSTRACT

Objective: The Royal Australian and New Zealand College of Psychiatrists (RANZCP) Clinical Memorandum Therapeutic Use of Psychedelic Substances May 2020 (Memorandum) advises against clinical use of 3,4-methylenedioxymethamphetamine (MDMA) and psilocybin outside research settings. This paper critically evaluates the evidentiary basis underpinning that position. **Methods:** A structured review of all references cited in the RANZCP memorandum was conducted, comparing cited claims with original source material. Supplementary searches of peer-reviewed literature, clinical trial registries, regulatory documents, and relevant legislation in Australia and New Zealand were undertaken to contextualise and update the evidence base. **Results:** Multiple discrepancies were identified between the memorandum's claims and the cited literature, including misinterpretation of sources, selective reporting, and reliance on outdated data. Contemporary evidence indicates that, when administered as adjuncts to psychotherapy in controlled clinical settings, MDMA and psilocybin demonstrate favourable safety profiles and emerging efficacy for treatment-resistant psychiatric conditions. Reported risks are predominantly associated with non-clinical or uncontrolled use. **Conclusion:** The current RANZCP position appears to be based on an incomplete and, in some instances, inaccurate appraisal of the available evidence. Given increasing international regulatory developments and clinical trial outcomes, there is a need

for ongoing review of policy positions, alongside consideration of ethical and public health implications, including risks associated with unsupervised use.

Key points

The RANZCP Memorandum concludes that Psychedelic-Assisted Therapy (PAT) should remain restricted to research settings and not be made available to patients outside clinical trials. This position is presented as evidence-based; however, a detailed review reveals substantial limitations in the memorandum's interpretation and use of the literature.

Key issues identified include:

- **Conceptual misclassification:** The Memorandum asserts that MDMA is "*not technically a psychedelic*", relying on legal rather than pharmacological criteria. This position is inconsistent with established scientific literature describing MDMA's pharmacodynamics, receptor activity, and therapeutic application within psychedelic-assisted psychotherapy.
- **Inaccurate generalisation of illegality:** The Memorandum characterises psychedelics as uniformly "illicit" in Australia and New Zealand. This is misleading, as several psychedelic substances (e.g., ketamine, ibogaine, harmala alkaloids) are legally used in therapeutic contexts or exist within regulated medical frameworks.
- **Misrepresentation of psychiatric risk**: The Memorandum cites literature suggesting associations between MDMA, psilocybin, and psychosis. Examination of the referenced studies indicates that these claims are unsupported, with reported cases largely involving polysubstance use or non-clinical settings rather than controlled therapeutic administration.
- **Understatement of the evidence base:** The Memorandum minimises the scale and duration of clinical research into psychedelic therapies, omitting substantial pre-prohibition data and underreporting the number of modern clinical trials and participants.
- **Selective interpretation of scientific uncertainty:** While highlighting incomplete understanding of neurobiological mechanisms, the memorandum overlooks extensive existing research in neuropsychopharmacology and neuroimaging that informs current therapeutic models.
- **Incorrect claims regarding international regulation:** The Memorandum states that no jurisdictions have regulated psychedelic therapy. In contrast, multiple countries have implemented compassionate use, expanded access schemes, or jurisdiction-specific regulatory pathways enabling controlled clinical use.

Collectively, these issues suggest that the RANZCP position is informed by selective, outdated, or inaccurately interpreted evidence. A comprehensive reassessment is warranted to ensure that clinical and policy recommendations reflect the current state of scientific knowledge.

1. Introduction

In Australia, there are active public submissions from the charitable organisation Mind Medicine Australia (MMA) to reschedule MDMA and psilocybin from Schedule 9 (S9; prohibited substances) to Schedule 8 (S8; controlled drugs) under the *Poisons Standard October 2021* (Cth) (MMA, 2020b). MDMA, a synthetic compound sometimes present in illicit 'ecstasy', and psilocybin, a naturally occurring tryptamine found in certain mushroom species, have been proposed as adjuncts to psychotherapy for individuals with Treatment-Resistant Depression (TRD) and Treatment-Resistant Post-Traumatic Stress Disorder (TR-PTSD)[2]. Rescheduling would permit strictly regulated clinical access within medically supervised environments.

The RANZCP, in its Memorandum, adopts a precautionary stance, recommending that PAT remain confined to research settings (RANZCP, 2020). The memorandum emphasises perceived limitations in the current evidence base and argues that clinical

[2] TR-PTSD is not a formal diagnostic category in the Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-5). The term TR-PTSD is used in this application to describe the psychopathology of PTSD that persists despite adequate treatment attempts with conventional pharmacological and psychotherapeutic interventions.

application outside formal trials is premature. Notably, both MDMA- and psilocybin-assisted therapies have been designated as "*breakthrough therapies*" by the United States Food and Drug Administration (FDA), indicating preliminary evidence of substantial improvement over existing treatments and enabling accelerated clinical development pathways.

Despite the rapid evolution of the international evidence base, the RANZCP memorandum has exerted disproportionate influence on Australian regulatory decision-making. The Therapeutic Goods Administration (TGA), in its interim determinations regarding compassionate access pathways, relied heavily on the Memorandum as a source of clinical guidance. This reliance is consequential, as it directly affects access for patients with severe, treatment-resistant psychiatric conditions.

However, the evidentiary foundation of the RANZCP position has not been subjected to systematic scrutiny. Given the increasing volume of clinical trial data, regulatory developments in multiple jurisdictions, and growing public and professional interest in PAT, it is essential to critically evaluate whether the memorandum accurately represents the current state of scientific knowledge.

This paper undertakes a detailed analysis of the RANZCP Memorandum by systematically examining its cited evidence, assessing the accuracy of its interpretations, and situating its claims within the broader contemporary literature. In doing so, it aims to determine whether the memorandum provides a reliable basis for clinical and regulatory decision-making in Australia and New Zealand.

2. Methodology

2.1. Study type

This study is a structured critical review and qualitative comparative analysis of the RANZCP Memorandum. The objective was to evaluate the accuracy, completeness, and contextual validity of the evidence used to support its conclusions.

All references cited within the RANZCP Memorandum were systematically examined. Claims made in the Memorandum were cross-checked against the original source material to assess consistency between cited evidence and its interpretation. Discrepancies were identified and categorised, including misinterpretation, selective citation, outdated evidence, and omission of relevant context.

The analysis was qualitative and comparative, evaluating whether the RANZCP Memorandum accurately reflects the broader contemporary evidence base relating to MDMA- and psilocybin-assisted therapy.

2.2. Search strategy

Targeted literature searches were conducted across Google Scholar, PubMed, and ScienceDirect to identify relevant studies on MDMA- and psilocybin-assisted therapies. Search terms included combinations of "MDMA", "psilocybin", "psychedelic therapy", "psychedelic-assisted therapy", "PAT", "safety", "efficacy", "clinical trials", "PTSD", and "depression".

No strict date restrictions were applied; however, emphasis was placed on contemporary literature, particularly studies published from 2000 onwards and recent phase II and phase III clinical trials. Reference lists of key articles were also reviewed to identify additional relevant sources.

Clinical trial registries, including ClinicalTrials.gov, were searched to identify completed and ongoing trials relating to MDMA and psilocybin. Regulatory and policy documents were identified through targeted searches of government and institutional websites, including those of the TGA and relevant international bodies.

2.3. Limitations

This study has several limitations. First, the analysis was qualitative and interpretive, and therefore subject to potential author bias in the identification and classification of discrepancies. While efforts were made to systematically cross-check all cited references, the assessment of misinterpretation or omission involves a degree of subjective judgement.

Second, this review did not employ a formal systematic review methodology (e.g., PRISMA framework), and therefore may not capture all relevant literature. The search strategy was targeted rather than exhaustive, prioritising key clinical studies, reviews, and regulatory materials most relevant to the claims made by the RANZCP.

Third, the rapidly evolving nature of psychedelic research means that newer studies may have emerged after the completion of this analysis. As such, conclusions should be interpreted within the context of the evidence available at the time of review.

Finally, this study focuses specifically on the evidentiary basis of the RANZCP memorandum and does not independently evaluate the full clinical efficacy or long-term safety of MDMA- or psilocybin-assisted therapy beyond the scope necessary for this critique.

3. Results

3.1. Conceptual classification of MDMA as a psychedelic

The Memorandum states that MDMA is "*not technically a psychedelic*":

> Though technically not a psychedelic, MDMA is included as it is similar to psychedelics with regard to legal impediments to research and potential therapeutic methods.

This classification is difficult to sustain on pharmacological, structural, and therapeutic grounds. "*Legal impediments*" and "*potential therapeutic methods*" are not the only relevant criteria for determining whether MDMA belongs within the psychedelic field. MDMA's central-acting mechanisms have been described as psychedelic (Nutt, 2019; Steele et al., 1994), and its pharmacodynamics include monoamine release, serotonin transporter modulation, and activity involving serotonin subtype-2A (5-HT_{2A}) receptors (Amoroso, 2015). 5-HT_{2A} receptors are central to classical serotonergic psychedelic pharmacology (Jalal, 2018; Moreno et al., 2011).

MDMA also interacts with dopamine subtype-2 (D_2) receptors, which are implicated in the effects of lysergic acid diethylamide (LSD) and salvinorin A (Amoroso, 2015; Giacomelli et al., 1998; Seeman et al., 2009). In addition, MDMA has been described as a psychedelic phenylethylamine substituted amphetamine (Schmidt, 1987; Trachsel, 2012). Other substituted amphetamine phenylethylamines are classified as psychedelics, including 3,4-methylenedioxyamphetamine (MDA), 2,5-dimethoxy-4-methylamphetamine (DOM), and 2,5-dimethoxy-4-bromophenylamine (2C-B) (Baggott et al., 2019; Eckler et al., 2003; Papaseit et al., 2018). MDA is also MDMA's major hepatic metabolite and is itself viewed as a classic psychedelic.

Accordingly, the Memorandum's claim that MDMA is "*not technically a psychedelic*" rests on an unduly narrow framing and does not adequately reflect the pharmacological and clinical literature.

3.2. Generalisation of psychedelics as "illicit"

The Memorandum states:

> Psychedelic substances are illicit and are not registered for any use by the Therapeutic Goods Administration (TGA) in Australia or Medsafe in New Zealand. They cannot be prescribed or administered outside of properly approved research trials.

This statement does not reflect the complexity of the regulatory landscape. The term "*illicit*" is applied broadly in the Memorandum without distinguishing between recreational prohibition and regulated medical or research use. In Australia, substances that are entirely prohibited due to risks to public health are listed under Schedule 10 (S10; Substances of such danger to health as to warrant prohibition of sale, supply and use) of the *Poisons Standard October 2021* (Cth). However, psychedelic substances are not uniformly classified under S10, and their regulatory status varies considerably.

Several substances with psychedelic properties are legally available or regulated within therapeutic or medical frameworks, including ketamine, ibotenic acid, harmala alkaloids, ibogaine, *N*,*N*-dimethyltryptamine (DMT), and methysergide. These substances may fall under differing regulatory categories, including controlled prescription, research-only access, unscheduled status, or conditional therapeutic use.

Accordingly, the phrase "*psychedelic substances*" encompasses multiple classes of compounds subject to different controls in Australia and New Zealand, rather than a single category of uniformly "*illicit*" substances. For example, *Acorus calamus* is prohibited for therapeutic use in Australia under S10, demonstrating that full prohibition applies only to specific substances rather than the class as a whole.

3.3. Medically regulated psychedelics in Australia and New Zealand

The Memorandum makes generalised statements regarding the prohibition of psychedelic substances in medical contexts. However, the regulatory status of these substances in Australia and New Zealand is heterogeneous and includes multiple pathways for controlled or approved use.

3.3.1. MDMA

MDMA has been classified as a B1 controlled drug in New Zealand since 2005 (New Zealand Legislation, 2005). B1 includes controlled medicines such as morphine, methadone, medicinal cannabis, and amphetamine (New Zealand Legislation, 1975). This classification allows, in principle, for prescription by medical practitioners with appropriate regulatory approval (Ministry of Health, 2019), although no such approvals are known to the authors.

In Australia, MDMA is federally classified as a S9. This permits use in research settings and allows patient access through the TGA via the Special Access Scheme-B (SAS-B) (Australian Government, 1989). Several patients with treatment-resistant conditions have been approved to receive MDMA under SAS-B (MMA, 2020a). However, access is further complicated by state-level regulation, where jurisdictions such as New South Wales and Western Australia prohibit therapeutic use despite federal approval, while Victoria provides access through a permit system.

3.3.2. Ketamine

Ketamine is described in multiple scientific studies as a psychedelic and has an established history of use in PAT. Between 1985 and 1995, ketamine was studied in over 1,000 participants in psychotherapeutic contexts, and more recent work has renewed its clinical application (Bowdle et al., 1998; Kolp et al., 2014; Krupitsky & Grinenko, 1997; Lim, 2003).

The TGA has approved ketamine (ingredient ID: 70736) and esketamine (ingredient ID: 114417) for therapeutic use in Australia, with 13 medicines currently listed on the Australian Registry of Therapeutic Goods (ARTG) (TGA, 2020).

3.3.3. Ibotenic acid and muscimol

Psychedelic *Amanita spp.* contain the GABAergic isoxazoles ibotenic acid and muscimol, with documented historical entheogenic use (Falandysz et al., 2020; Feeney, 2010; Ott, 1996; Trutmann, 2012). These species are not scheduled under the *Poisons Standard October 2021* (Cth) or the *Misuse of Drugs Act 1975* (New Zealand), although they are prohibited for use in food under the *Food Standards Australia New Zealand Act 1991* (Cth) (Food Standards Australia New Zealand, 2015).

Ibotenic acid is unscheduled in both jurisdictions and has been approved by the TGA for use in therapeutic biological devices (ingredient ID: 105657). Muscimol is S9 in Australia but remains unscheduled in New Zealand.

3.3.4. Harmala alkaloids

Harmala alkaloids, associated with Ayahuasca preparations (Callaway et al., 1996), are federally S9 substances but may be unscheduled when used in certain herbal or therapeutic preparations. The TGA provides a protocol for their therapeutic use.

Peganum harmala (ingredient ID: 83330) has been approved for use in medicine and is used as a substitute for *Banisteriopsis caapi* in Ayahuasca preparations (Kaasik et al., 2021; Mina et al., 2015; Moloudizargari et al., 2013). These compounds have a documented history of entheogenic and cultural use.

3.3.5. Ibogaine

Ibogaine and noribogaine are classified as Schedule 4 (S4; prescription-only medicines) in Australia and are available by prescription without additional restrictions in New Zealand (Medsafe, 2020). This scheduling was informed by the National Drugs and Poisons Schedule Committee (NDPSC) recommendations based on the Medicines Classification Committee (MCC) reasoning (NDPSC, 2010), including:

i. The need for supervised medical use to reduce self-treatment risks;

ii. The need to control supply and importation;

iii. Evidence suggesting lower mortality compared to methadone;

iv. Risks associated with unsupervised use in response to media attention.

These considerations demonstrate that medical regulation may be used to mitigate harm associated with unsupervised use.

3.3.6. DMT

DMT is classified as S9 in Australia and a Class A controlled drug in New Zealand. However, the TGA has approved several DMT-containing plants for therapeutic use.

The ARTG lists one medicine containing *Acacia longifolia* (ARTG ID: 176056), with approximately 1–1.5 mg of DMT per mL (Lim, 2014).

Table 1. DMT-containing plants approved for use in medicines by TGA in Australia

Plant	Approved medical ingredient ID	Psychedelic	Amount
Acacia longifolia	86827	DMT	0.2-0.3% (Lim, 2014)
Phalaris arundinacea	87004	DMT NMT 5-MeO-DMT 5-MeO-NMT β-Carbolines	0.2-0.7% (Østrem, 1987; Woods & Clark, 1971)
Mucuna pruriens	83253	DMT Bufotenine	Unspecified (Kavitha & Thangamani, 2014)

NMT *N*-Methyltryptamine; 5-MeO-DM 5-Methoxy-*N*,*N*-dimethyltryptamine; 5-MeO-NMT 5-Methoxy-*N*-methyltryptamine; β-Carbolines Harmala alkaloid family; Bufotenine 5-Hydroxy-dimethyltryptamine (5-OH-DMT)

3.4. International patterns of medically controlled use

There is increasing media and public interest in MDMA- and psilocybin-assisted therapies for conditions including depression, PTSD, Generalised Anxiety Disorder (GAD), Social Anxiety Disorder (SAD), and addiction. In recent years, these therapies have received substantial coverage in Australian media, including Australian Broadcasting Corporation (ABC), 7NEWS, The Sydney Morning Herald, and 60 Minutes (Abo, 2020; Daoud, 2020; Malcom & Bedi, 2018; McCauley, 2020; Taylor, 2020).

Both MDMA- and psilocybin-assisted therapies have been granted "*breakthrough therapy*" status by the FDA, which is acknowledged in the Memorandum (Feduccia et al., 2019; Nichols, 2020). Additional regulatory developments include the FDA expanded access program for MDMA in PTSD, compassionate use of MDMA in Israel, and clinical use in Switzerland (Brewerton et al., 2020; MAPS, 2019b; Sessa et al., 2019).

Psilocybin therapy has been legalised for medical use in Oregon, United States and Canada has approved psilocybin-assisted therapy for depression and end-of-life anxiety (Ballotpedia, 2020; Carpenter, 2020; Semley, 2020). The Canadian Health Minister has granted therapeutic access under section 56(1) of the *Controlled Drugs and Substances Act* (Canada) (Wood et al., 2019). Clinics providing PAT have opened in Toronto, New York City, Los Angeles, and Chicago, with additional access pathways emerging internationally (Stella, 2020).

In Australia, the TGA has granted SAS-B approvals for MDMA and psilocybin. However, state-level restrictions may prevent implementation despite federal approval, resulting in a comparatively restrictive framework.

3.5. Regulatory interest and self-medication risk

The NDPSC, TGA, and MCC have previously identified that increased public awareness of psychedelic therapies may elevate the risk of self-medication where regulated medical pathways are unavailable (NDPSC, 2010).

The Memorandum states:

> Currently psychedelic therapy is not regulated for use in any country.

This statement does not account for expanded access, compassionate use, and jurisdiction-specific regulatory frameworks. While these pathways do not constitute full medical approval, they represent formal regulatory mechanisms enabling controlled clinical use.

Ibogaine provides a relevant comparator. It is available by prescription in Australia and New Zealand and is administered in clinical settings internationally, including in Canada, Mexico, Gabon, South Africa, Costa Rica, and the Bahamas (Avante Ibogaine Institute, 2020; Bwiti Healing, 2019; IbogaQuest, 2020; IbogaSoul, 2020; Inner Realms Center, 2020; Transcend Clinic, 2020; Underwood, 2020). Ayahuasca has also been used therapeutically in structured environments, including rehabilitation programs in Brazil (Rocha & Rossi, 2019; Romero, 2015),

These examples demonstrate that regulatory models exist for controlled therapeutic use, particularly where there is concern regarding unsupervised self-medication.

3.6. Safety profile of medicinal MDMA

The distinction between uncontrolled use and medically supervised administration is central to evaluating MDMA safety. Morbidity and mortality associated with MDMA have been reported in uncontrolled non-clinical settings (Sessa et al., 2019), while serious adverse effects in clinical contexts have been rare and non-life-threatening (MAPS, 2019a).

The Memorandum states:

> Clinical trials have demonstrated safety profile; for example, 760 individuals have participated in the MAPS' MDMA trials with only one serious adverse event reported [17] relating to tachycardia and increased blood pressure.

This figure appears to rely on an outdated MAPS poster (MAPS, n.d.), which itself reports "*over 780 human subjects*". Earlier and more comprehensive sources indicate higher participant numbers, including 811 participants reported in 2013 (MAPS, 2013). More recent data suggest substantially larger cumulative totals, including over 1,700 participants in clinical trials and thousands more in pre-prohibition therapeutic use (MAPS, 2020; MAPS, 2021).

Table 2. MAPS reported trial participants who have received MDMA

Year	# of participants	Source
Pre-1987 (pre-prohibition)	≈ 500,000 doses of MDMA administered to patients globally	Investigator's Brochure (MAPS, 2020, p. 56)
2000-2012	811 cumulative	Investigator's Brochure (MAPS, 2013, p. 54)
until 2015	1,180 cumulative	Investigator's Brochure (MAPS, 2016, p. 92)
until 2016	1,280 cumulative	Investigator's Brochure (MAPS, 2017, p. 133)
until 2018	> 1,500 cumulative	Investigator's Brochure (MAPS, 2018a, p. 127)
until April 2020	1,431 (non-MAPS sponsored) 279 (MAPS sponsored **1,710 cumulative**	Investigator's Brochure (MAPS, 2020, p. 14)
until October 2020	1,434 (non-MAPS sponsored 341 (MAPS Sponsored) **1,775 cumulative**	Investigator's Brochure (MAPS, 2021, p. 54)

Historical data indicate approximately 500,000 doses of MDMA administered in psychotherapy prior to prohibition, with reports of minimal complications (MAPS, 2018b; Passie, 2018). Since 2009, more than 34 MDMA clinical trials and over 50 psychedelic clinical trials have been completed (Table 3), exceeding the "*several trials*" described in the Memorandum.

MDMA's association with harm is primarily derived from recreational ecstasy use (Armenian et al., 2013). Key distinctions include unknown composition, uncontrolled dosing, polysubstance use, and absence of medical screening. In contrast, medicinal MDMA is pharmaceutical grade, administered in controlled settings with screening and therapeutic support (MMA, 2020a).

The estimated lethal dose of MDMA is 10–20 mg/kg, compared to therapeutic doses of 1–2 mg/kg, indicating a substantial safety margin (Jerome, 2007; MAPS, 2018b). This corresponds to a safety factor of approximately 5–20 between therapeutic and lethal dosing. For comparison, paracetamol has been described in the literature as having a safety factor of approximately 10 relative to its lethal dose (Wong, 2002). Clinical data indicate:

- Adverse events are rare in controlled settings (MAPS, 2019a)
- No evidence of dependence in therapeutic use (Kalant, 2001)

- No increase in illicit drug use following treatment (Sessa et al., 2019)

In Australia between 2000 and 2018, 243 deaths in recreational environments involved drug toxicity where MDMA was present (Roxburgh & Lappin, 2020). However, only 14 of these deaths were attributed solely to MDMA toxicity, without the involvement of other substances. This distinction highlights the role of polysubstance use and uncontrolled conditions in adverse outcomes.

In its Memorandum under "*Risks and side effects*", the RANZCP states:

> Frequent high dose MDMA can be neurotoxic (damaging to the nervous system) [16].

While this statement is applicable to high-dose recreational use, it does not reflect the conditions under which MDMA is administered in controlled clinical settings. In this context, such risks are more appropriately associated with misuse or abuse rather than medically supervised therapeutic use.

3.7. Safety profile of psilocybin

3.7.1. Hallucinogen induced psychotic disorder

The Memorandum associates psychedelics with risks such as psychosis and Hallucinogen Persisting Perception Disorder (HPPD), stating:

> Psychedelics, when misused, can cause psychosis (hallucinogen induced psychotic disorder) as well as Hallucinogen Persisting Perception Disorder (HPPD). [18, 19] This is a potential long-term risk factor following psychedelic therapy, though this has not been investigated in research trials.

The qualifier "*when misused*" is critical. However, the use of references [18, 19] in the Memorandum does not support the implication that psilocybin or MDMA are associated with these outcomes in controlled therapeutic settings.

Cross-examination of the cited sources reveals important discrepancies. The paper cited as reference [18] Martinotti et al. (2018) identifies associations between HPPD and substances including cannabis, LSD, phencyclidine (PCP), and polysubstance use, including cannabis co-administered with MDMA. However, it does not attribute HPPD specifically to psilocybin or MDMA in isolation. Similarly, the meta-analysis cited as reference [19] Murrie et al. (2020) reports that the most common cause of drug-induced psychosis is alcohol. Of 40,783 individuals included in the analysis, only 208 cases (0.5%) were associated with hallucinogens, and these occurred in uncontrolled settings without specification of individual compounds.

The Memorandum does not distinguish these contexts and, in doing so, extends conclusions beyond what is supported by the cited evidence. This represents a mischaracterisation of the underlying literature.

Population-level data further challenge the association between psychedelics and psychosis. A large cohort study (n = 135,000) found no increased risk of mental health disorders, including psychosis, depression, anxiety, or suicidality, among individuals who had used psychedelics ((Johansen & Krebs, 2015). In uncontrolled settings, adverse psychological outcomes have been reported at low rates; for example, a self-reported survey of 1,993 individuals found 0.15% reporting enduring psychosis and 0.15% reporting suicide attempts following challenging experiences (Carbonaro et al., 2016). These findings remain context-dependent and do not reflect controlled clinical use.

In contrast, clinical studies of psilocybin administered in controlled environments report minimal adverse effects and no evidence of persistent psychosis or HPPD (Carhart-Harris et al., 2018; Dos Santos et al., 2018; Strassman, 1984). Early therapeutic use of pharmaceutical psilocybin (Indocybin®) was similarly reported to be without complication (Passie et al., 2002).

Taken together, the available evidence indicates that risks of psychosis and HPPD are primarily associated with uncontrolled use and are not demonstrated in clinical settings. The Memorandum's presentation does not adequately reflect this distinction.

3.7.2. Toxicity and mortality

The Memorandum does not engage with the toxicological profile of psilocybin. Available evidence indicates that psilocybin has a low toxicity profile. The estimated lethal dose in humans is approximately 6 g, which is around 300 times greater than a typical therapeutic dose of 20 mg(Gable, 2004).

Fatalities associated with psilocybin are extremely rare. Reviews of the literature report only two deaths attributable to direct psilocybin overdose internationally since 1960 (van Amsterdam et al., 2011). Additional reports in forensic and pharmacological literature similarly describe fatal intoxication from psilocybin-containing mushrooms as uncommon (Gonmori & Yoshioka, 2002; McCawley et al., 1962).

For context, national data from the Australian Bureau of Statistics (ABS) indicate substantially higher mortality associated with commonly prescribed psychiatric medications, including 276 deaths from antidepressants and 663 deaths from anti-anxiety medications in 2016 alone (ABS, 2018).

Furthermore, the estimated lethal intake of fresh psilocybin-containing mushrooms is approximately 17 kg, a quantity that is practically implausible to consume (van Amsterdam et al., 2011).

Overall, the toxicological evidence indicates that psilocybin has a wide safety margin relative to therapeutic dosing, with an extremely low incidence of fatal outcomes. This profile is not reflected in the Memorandum.

3.8. Neurobiological evidence

The Memorandum states:

> Much about the neuroscience of psychedelics remains unknown, although there are theories that they heighten emotional responses and encourage people to confront their disorder actively, which can prompt enduring shifts in mind-set.

While some mechanisms remain under investigation, substantial research exists. Psilocybin has been shown to alter functional connectivity and Default Mode Network (DMN) activity (Carhart-Harris & Goodwin, 2017). MDMA neuropharmacology and its therapeutic mechanisms in PTSD are well documented (Bremner et al., 2005; Doss et al., 2018; Feduccia & Mithoefer, 2018).

Areas of ongoing research include the mechanisms underlying "*mystical experiences*" and their relationship to therapeutic outcomes (Griffiths et al., 2008; Griffiths et al., 2011).

3.9. Further research and access

The Memorandum states:

> Further research is required to assess the efficacy, safety and effectiveness of psychedelic therapies to inform future potential use in psychiatric practices. Research into the clinical use of psychedelic substances should only occur under research trial conditions that include oversight by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes.

Further research is warranted; however, current evidence includes phase 3 trials, breakthrough therapy designation, and remission rates of 60–80% in TRD and TR-PTSD (Agin-Liebes et al., 2020; MAPS, 2020).

Given the burden of mental illness in Australia (ABS, 2018; Mills et al., 2011), the exclusion of case-by-case clinical access requires strong evidentiary justification. Comparable medical treatments are routinely used despite incomplete mechanistic understanding (Hedya et al., 2020; Toussaint et al., 2010).

In the context of high rates of depression, PTSD, and suicide in Australia (ABS, 2018; Qi et al., 2012), there is a need for clearly substantiated reasons to withhold access to these therapies for patients who have exhausted conventional treatment options.

A lack of complete understanding of mechanisms of action has not prevented the widespread use of many established medicines, including paracetamol, lithium, general anaesthetics, and modafinil (Gerrard & Malcolm, 2007; Hedya et al., 2020; Mashour et al., 2005; Pavel et al., 2020; Toussaint et al., 2010). For example, the precise mechanism by which lithium stabilises mood remains unclear, despite its widespread clinical use and known toxicity risks (Hedya et al., 2020; Jakobsson et al., 2017; Oruch et al., 2014; Risby et al., 1991; Treiser et al., 1981).

Cost considerations are also relative. Short-duration treatments with sustained remission may represent lower long-term cost compared to chronic pharmacotherapy.

The Memorandum also states:

> The treatments can be expensive, and the short timeframes of application (1–2 sessions) suggested by early research put limits on the potential profitability of psychedelic therapies; as a result, there are few pharmaceutical companies supporting research.

The Memorandum also suggests that psychedelic therapies may be limited by cost and lack of pharmaceutical investment due to short treatment durations. However, characterising the evidence base as "*early research*" is inconsistent with the volume of historical and contemporary data. Furthermore, long-term treatment with conventional pharmacotherapies may result in greater cumulative cost compared to shorter-duration interventions that achieve sustained remission.

There is also significant evidence supporting the safety, efficacy, and effectiveness of MDMA- and psilocybin-assisted therapies in controlled settings, as well as their regulated or permitted use in jurisdictions such as Canada, Switzerland, Israel, and the United States.

Table 3. A non-exhaustive list of completed psychedelic studies from 2009 till May 2020

#	Year complete	Psychedelic substance	Condition or illness	Reference
1	2020	MDMA	PTSD	https://clinicaltrials.gov/ct2/show/NCT03537014
2	2020		PTSD	https://clinicaltrials.gov/ct2/show/NCT03485287
3	2020		GAD	https://clinicaltrials.gov/ct2/show/NCT02427568
4	2019		SAD in Autistic Adults	https://clinicaltrials.gov/ct2/show/NCT02008396
6	2019		PTSD	https://clinicaltrials.gov/ct2/show/NCT02876172
6	2019		Substance-Related Disorders	https://clinicaltrials.gov/ct2/show/NCT01148342
7	2019		Mood, Performance	https://clinicaltrials.gov/ct2/show/NCT02033707
8	2018		PTSD	https://clinicaltrials.gov/ct2/show/NCT01689740
9	2018		PTSD	https://clinicaltrials.gov/ct2/show/NCT01793610
10	2018		Effects on Emotional and Social Memories	https://clinicaltrials.gov/ct2/show/NCT03050541
11	2018		Substance-related and Mood Disorders	https://clinicaltrials.gov/ct2/show/NCT01270672
12	2018		Substance-related and Mood Disorders	https://clinicaltrials.gov/ct2/show/NCT01386177
13	2018		PTSD	https://clinicaltrials.gov/ct2/show/NCT01211405
14	2018		GAD	https://clinicaltrials.gov/ct2/show/NCT02954562
15	2018		Emotion Processing	https://clinicaltrials.gov/ct2/show/NCT03019822
16	2018		Social Cognition	https://clinicaltrials.gov/ct2/show/NCT01616407
17	2017		PTSD	https://clinicaltrials.gov/ct2/show/NCT00353938
18	2017		PTSD	https://clinicaltrials.gov/ct2/show/NCT01958593
19	2017		PTSD	https://clinicaltrials.gov/ct2/show/NCT02102802
20	2017		PTSD	https://clinicaltrials.gov/ct2/show/NCT01458327
21	2016		Substance-related and Mood Disorders	https://clinicaltrials.gov/ct2/show/NCT01951508
22	2016		Emotional Effects	https://clinicaltrials.gov/ct2/show/NCT01465685
23	2016		Substance-Related Disorders	https://clinicaltrials.gov/ct2/show/NCT01771874
24	2015		PTSD	https://clinicaltrials.gov/ct2/show/NCT00090064
25	2014		Drug Addiction	https://clinicaltrials.gov/ct2/show/NCT01849419
26	2014		Amphetamine-Related Disorders	https://clinicaltrials.gov/ct2/show/NCT02232789
27	2013		MDMA Discontinuation Syndrome	https://clinicaltrials.gov/ct2/show/NCT01053403
28	2013		Substance-related and Mood Disorders	https://clinicaltrials.gov/ct2/show/NCT01136278
29	2013		Substance-related and Mood Disorders	https://clinicaltrials.gov/ct2/show/NCT00990067
30	2013		Mechanism of Action	https://clinicaltrials.gov/ct2/show/NCT00838305
31	2013		Substance-related and Mood Disorders	https://clinicaltrials.gov/ct2/show/NCT00886886
32	2011		Pharmacokinetics	https://clinicaltrials.gov/ct2/show/NCT01447472
33	2011		Hangover	https://clinicaltrials.gov/ct2/show/NCT01400204
34	2009		Substance-related and Mood Disorders	https://clinicaltrials.gov/ct2/show/NCT00895804
35	2020	Psilocybin	Distress, Depression, Grief	https://clinicaltrials.gov/ct2/show/NCT02950467
36	2020		Healthy	https://clinicaltrials.gov/ct2/show/NCT02163707
37	2019		Persisting Effects	https://clinicaltrials.gov/ct2/show/NCT02971605
38	2019		Healthy	https://clinicaltrials.gov/ct2/show/NCT02145091
7	2019		Mood, Performance	https://clinicaltrials.gov/ct2/show/NCT02033707
39	2018		Depression, GAD, Cancer	https://clinicaltrials.gov/ct2/show/NCT00465595
40	2016		Healthy	https://clinicaltrials.gov/ct2/show/NCT00802282
41	2014		Pharmacology, Therapeutic Uses	https://clinicaltrials.gov/ct2/show/NCT01988311
42	2013		GAD	https://clinicaltrials.gov/ct2/show/NCT00302744
43	2019	Ayahuasca	Treatment-Resistant Depression	https://doi.org/10.1017/S0033291718001356
44	2019		Major Depression Disorder (MDD)	https://doi.org/10.3389/fpsyg.2019.0123
45	2017		MDD	https://clinicaltrials.gov/ct2/show/NCT02914769
46	2020	LSD	Microdose	https://clinicaltrials.gov/ct2/show/NCT04421105
16	2018		Emotion Processing	https://clinicaltrials.gov/ct2/show/NCT03019822
47	2019		Healthy	https://clinicaltrials.gov/ct2/show/NCT03321136
8	2019		Mood, Performance	https://clinicaltrials.gov/ct2/show/NCT02033707
48	2016		Healthy	https://clinicaltrials.gov/ct2/show/NCT01878942
49	2016		Personal Meaning	https://clinicaltrials.gov/ct2/show/NCT02451072
50	2015		Healthy	https://clinicaltrials.gov/ct2/show/NCT02308969
51	2014		GAD	https://clinicaltrials.gov/ct2/show/NCT00920387
8	2019	Mescaline	Mood, Performance	https://clinicaltrials.gov/ct2/show/NCT02033707
52	2013	MDA	Healthy	https://clinicaltrials.gov/ct2/show/NCT00823407

4. Discussion

The findings of this review demonstrate that the RANZCP Memorandum is not supported by a consistent, accurate, or comprehensive appraisal of the available evidence. Across conceptual definitions, regulatory characterisation, safety data, and representation of the clinical literature, multiple discrepancies were identified that collectively undermine the reliability of the Memorandum as a foundation for clinical or policy guidance (Brinzei, 2026).

First, the Memorandum adopts a restrictive and internally inconsistent conceptual framework. The classification of MDMA as "*not technically a psychedelic*" does not align with established pharmacological literature describing its serotonergic activity, including 5-HT_{2A} receptor involvement, and its classification within psychedelic phenylethylamines (Amoroso, 2015; Moreno et al., 2011; Trachsel, 2012). This definitional framing influences how subsequent evidence is interpreted.

Second, the Memorandum presents an oversimplified account of the regulatory landscape. The use of the term "*illicit*" as a blanket descriptor fails to distinguish between recreational prohibition and regulated therapeutic use. Evidence presented in this review demonstrates that multiple substances with psychedelic properties, including ketamine, ibogaine, and harmala alkaloids, are already regulated within medical frameworks in Australia and New Zealand (Medsafe, 2020; NDPSC, 2010; TGA, 2020). Internationally, expanded access and compassionate use pathways further demonstrate that controlled therapeutic use is already operational in several jurisdictions (Brewerton et al., 2020; MAPS, 2019a; Sessa et al., 2019).

Third, the Memorandum understates the scale of the evidence base. The characterisation of the literature as consisting of "*several*" trials is inconsistent with the documented volume of completed studies, including dozens of registered trials and decades of both pre- and post-prohibition data (MAPS, 2020; MAPS, 2021). Reliance on incomplete or outdated sources, such as summary-level materials rather than primary data, further weakens the evidentiary foundation.

Fourth, the Memorandum does not adequately distinguish between risks associated with uncontrolled use and those observed in medically supervised settings. Evidence reviewed indicates that morbidity and mortality associated with MDMA occur in uncontrolled environments (Sessa et al., 2019), whereas clinical studies report low rates of serious adverse events (MAPS, 2019a). Similarly, psilocybin-associated psychiatric risks are predominantly reported in uncontrolled contexts, with population-level data showing no increased risk of mental illness following use (Johansen & Krebs, 2015; Murrie et al., 2020). This distinction is critical for accurate risk assessment.

Fifth, the Memorandum does not fully engage with international regulatory developments. While acknowledging FDA "*breakthrough therapy*" designation (Feduccia & Mithoefer, 2018; Nichols, 2020), it does not account for expanded access programs, compassionate use frameworks, or jurisdiction-specific regulatory models. These mechanisms demonstrate that psychedelic therapies are already subject to structured regulatory oversight, even in the absence of full market approval.

Sixth, the Memorandum applies a precautionary standard that is not consistently applied across psychiatric practice. Many established treatments, including lithium and general anaesthetics, are used despite incomplete understanding of their mechanisms of action (Hedya et al., 2020; Pavel et al., 2020). The selective emphasis on uncertainty in the context of PAT suggests an asymmetry in evidentiary thresholds.

Seventh, the Memorandum does not sufficiently address the public health implications of restricted access. Increased awareness of MDMA and psilocybin, combined with limited clinical pathways, may contribute to self-medication in uncontrolled environments. This risk has been recognised in prior regulatory decisions, including the scheduling rationale for ibogaine (NDPSC, 2010), where supervised access was viewed as a harm-reduction strategy.

Taken together, these findings indicate that the Memorandum does not provide a balanced or comprehensive account of the current evidence base. The cumulative effect of definitional limitations, regulatory oversimplification, selective citation, and insufficient contextualisation of risk is a position that is more conservative than the evidence alone would support.

This does not imply that MDMA- or psilocybin-assisted therapies should be implemented without caution. Ongoing research is required to further define long-term outcomes, optimal protocols, and patient selection criteria. However, current evidence, including clinical trials, regulatory developments, and safety data, supports a more nuanced position that recognises both risks and therapeutic potential within controlled clinical frameworks.

A revised approach would involve transparent engagement with the full evidence base, clearer differentiation between recreational and clinical risk, and consideration of structured pathways for limited clinical access under regulatory oversight. Such an approach would better align with both the available data and the needs of patients with treatment-resistant conditions.

In its current form, the Memorandum does not meet this standard. A comprehensive revision is therefore warranted to ensure that clinical guidance accurately reflects contemporary scientific and regulatory evidence.

5. Conclusion

This review has identified substantial inconsistencies, omissions, and inaccuracies in the RANZCP Memorandum that collectively undermine its reliability as a foundation for clinical and regulatory guidance. Across conceptual classification, regulatory characterisation, safety evaluation, and representation of the evidence base, the Memorandum does not accurately reflect the current state of scientific knowledge.

The conclusions presented in the Memorandum are not supported by a comprehensive appraisal of the available literature. Key issues include restrictive and internally inconsistent definitions, oversimplification of regulatory frameworks, reliance on incomplete or outdated data, and insufficient differentiation between risks associated with uncontrolled use and those observed in medically supervised settings. These factors, taken together, result in a position that is more conservative than the evidence alone would support.

Current evidence, including phase 2 and phase 3 clinical trials, long-term safety data, and international regulatory developments, indicates that MDMA- and psilocybin-assisted therapies may be administered with favourable safety profiles and emerging efficacy in controlled clinical environments (Agin-Liebes et al., 2020; MAPS, 2020; MAPS, 2021). These findings are further supported by regulatory recognition, including FDA "*breakthrough therapy*" designation and the implementation of expanded access and compassionate use frameworks in multiple jurisdictions (Brewerton et al., 2020; Feduccia et al., 2019; Nichols, 2020).

In the context of treatment-resistant psychiatric conditions, where existing therapeutic options are often inadequate, the continued exclusion of case-by-case clinical access requires a clear and robust evidentiary justification. The Memorandum, in its current form, does not provide such justification. Furthermore, increasing public awareness of these therapies, combined with limited clinical pathways, may contribute to self-medication in uncontrolled environments, a risk previously recognised in regulatory decision-making (NDPSC, 2010).

This review does not advocate for unrestricted clinical use. Ongoing research, careful patient selection, and strict regulatory oversight remain essential. However, the available evidence supports a more proportionate and evidence-aligned approach than that reflected in the Memorandum, one that acknowledges both the risks and the therapeutic potential of these interventions.

As a leading authority in psychiatry, RANZCP has a responsibility to ensure that its clinical guidance is accurate, evidence-based, and responsive to evolving scientific and regulatory developments. A comprehensive revision of the Memorandum is therefore warranted. Such a revision should incorporate current clinical data, accurately represent regulatory frameworks, and clearly distinguish between recreational risk and medically supervised therapeutic use.

Without such revision, there is a risk that clinical guidance will remain misaligned with contemporary evidence and international practice, with potential consequences for both patient access and public health outcomes.

6. Questions for RANZCP

In light of the findings of this review, the following questions arise for RANZCP:

1. **Evidence Thresholds**

   What specific level and type of evidence does RANZCP consider sufficient to support case-by-case clinical access to MDMA- and psilocybin-assisted therapies, and how does this threshold compare to that applied to existing psychiatric treatments?

2. **Interpretation of Current Data**

   How does RANZCP reconcile its position with the existing body of clinical trial data, including phase 2 and phase 3 studies, reporting favourable safety and efficacy outcomes?

3. **Use of Evidence in the Memorandum**

   What methodology was used to select and interpret the evidence cited in the Memorandum, and how does RANZCP account for the discrepancies identified between cited sources and their interpretation?

4. **Regulatory Characterisation**

   On what basis does RANZCP characterise psychedelic substances as uniformly "*illicit*", given the documented variation in regulatory status across substances and jurisdictions?

5. **International Developments**

   How does RANZCP incorporate international regulatory developments, including expanded access, compassionate use, and jurisdiction-specific legal frameworks, into its policy positions?

6. **Risk Assessment Framework**

   How does RANZCP differentiate between risks associated with uncontrolled recreational use and those observed in medically supervised clinical settings when forming its recommendations?

7. **Public Health Implications**

   How does RANZCP address the potential for increased self-medication and unregulated use in the absence of accessible clinical pathways?

8. **Research Pathways and Timelines**

   What specific research does RANZCP consider necessary before revising its position, and what is the anticipated timeframe for this process?

9. **Access for Treatment-Resistant Patients**

   How does RANZCP justify the continued restriction of access for patients with treatment-resistant conditions who have exhausted conventional treatment options?

10. **Commitment to Revision**

    Will RANZCP commit to a formal review and update of the Memorandum to ensure alignment with current scientific evidence and regulatory developments?

These questions are intended to support transparent, evidence-based dialogue and to clarify the criteria underpinning RANZCP's current position on psychedelic-assisted therapies.

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