

**NIIM HREC AUTHORISED PRESCRIBER SCHEME (PSYCHEDELIC MEDICINES) APPLICATION APPROVAL PROCEDURES**

**1. Procedures Statement**

The aim of these procedures is to set out the processes for applications to the NIIM Human Research Ethics Committee (HREC) under the Therapeutic Goods Administration’s (TGA’s) Authorised Prescriber Scheme as it relates to the prescribing of psilocybin for treatment-resistant depression and MDMA for treatment of post-traumatic stress disorder (PTSD) only. Psilocybin and MDMA are *unapproved* therapeutic goods (not listed on the Australian Register of Therapeutic Goods) which are Schedule 8 (Controlled Drugs) only for the purposes of treatment of treatment-resistant depression (psilocybin) and PTSD (MDMA). Psilocybin and MDMA remain Schedule 9 drugs for all other medical indications. Unapproved goods have not been assessed by the TGA for safety, quality or efficacy. The prescribing of psilocybin or MDMA is taken to be within the context of psychedelic-assisted therapy (PAT), defined as ‘a treatment focused on psychotherapy sessions, in highly supportive and structured environments, including the administration of a psychedelic drug as a tool to assist the psychotherapy. A course of treatment typically includes preparation sessions, active dosing session(s) where the psychedelic drug is administered, and integration sessions’[[1]](#footnote-1).

The related Policy is the *NIIM HREC Authorised Prescriber Scheme (Psychedelic Medicines) Application Approval Policy.*

Supporting documents provided by the TGA include:

* *Authorised Prescriber Scheme. Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors Version 5.2 (December 2022)[[2]](#footnote-2)*
* *Access To MDMA (3,4-Methylenedioxy-Methamphetamine) And Psilocybin For Therapeutic Purposes. Information For Psychiatrist Prescribers Version 2.0, February 2023[[3]](#footnote-3)*

**2. Procedures Application**

These procedures and its related policy apply only to applications by registered Australian psychiatrists wishing to apply under the TGA’s Authorised Prescriber Scheme to be able to prescribe psilocybin for treatment-resistant depression and/or MDMA for PTSD which are unapproved Schedule 8 (Controlled Drugs) therapeutic goods.

**3. Definitions**

**ARTG** Australian Register of Therapeutic Goods

**Ancillary PAT Therapists:** other suitably qualified professionals involved in PAT therapy other than the authorised prescriber.

**Authorised Prescriber** Individual medical practitioner approved to use an unapproved therapeutic good under the TGA’s Authorised Prescriber Scheme.

**Dyad (also called Treating Dyad):** pair of PAT therapists, of which at least one must be female, who are (both) present during the dosing event to guide the patient through the experience; at least one of them is expected to be involved in delivery of the PAT preparation and integration sessions as part of overall PAT delivery.

**HREC** Human Research Ethics Committee

**Lead PAT Therapist:** Considered to be the senior therapist in a PAT dyad. The minimum qualification for a lead therapist is expected to be a minimum of a clinical psychologist (and may be a psychiatrist). **MDMA** 3,4‑methylenedioxy‑methamphetamine

**NIIM** National Institute of Integrative Medicine

**PAT** Psychedelic Assisted Therapy (pl. Therapies): ‘a treatment focused on psychotherapy sessions, in highly supportive and structured environments, including the administration of a psychedelic drug as a tool to assist the psychotherapy. A course of treatment typically includes preparation sessions, active dosing session(s) where the psychedelic drug is administered, and integration sessions’[[4]](#footnote-4)

**PTSD** post-traumatic stress disorder

**RANZCP** Royal Australian and New Zealand College of Psychiatry (RANZCP)

**Secondary PAT Therapist:** part of the treating Dyad, working alongside the Lead PAT Therapist.

**SUSMP** Standard for the Uniform Scheduling of Medicines and Poisons

**TGA** Therapeutic Goods Administration

**Unapproved Goods** Therapeutic goods that are not listed on the Australian Register of Therapeutic Goods and therefore not approved by the TGA

**4. TGA Authorised Prescriber Scheme: Overview**

4.1 Under the TGA’s Authorised Prescriber Scheme, the TGA may grant a medical practitioner authority to prescribe a specified unapproved therapeutic product for particular indications to a class of patients in their immediate care. In the case of psilocybin and MDMA, the medical practitioner must be a registered psychiatrist and a Fellow of the Royal Australian and New Zealand College of Psychiatrists (RANZCP). The practitioner must:

* have training and expertise appropriate for the condition being treated and the proposed use of the unapproved therapeutic product;
* have a therapeutic relationship with the patient for whom they are prescribing the unapproved therapeutic product (psychedelic medicine)
* be able to determine the needs of the patient and be directly responsible for assessment of the suitability of the patient for PAT therapy
* monitor the outcomes of the therapy
* hold appropriate professional medical indemnity insurance relevant to the practice of psychedelic-assisted therapies and the prescribing of the unapproved therapeutic products (psychedelic medicines)

It is understood that the use of psychedelic medicines occurs within the context of psychedelic assisted therapies (PAT) and that delivery of PAT may involve other ancillary therapists. Whilst there is no requirement that the psychiatrist who is the authorised prescriber be present throughout the entire PAT treatment process, the psychiatrist who is the authorised prescriber is not permitted to delegate the prescribing of the unapproved therapeutic product nor the therapeutic assessment of the patient and their suitability for PAT to another practitioner.

4.2 To become an authorised prescriber of psilocybin and/or MDMA, the registered psychiatrist must first obtain approval from a human research ethics committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC) to prescribe the product(s) before then applying for final approval by the TGA. The TGA grants the final approval for authorised prescriber status.

4.3 Once a psychiatrist becomes an Authorised Prescriber of MDMA and/or psilocybin, they are not required to notify the TGA each time they prescribe the unapproved product. However, they are required to report the number of patients treated with the unapproved product twice yearly to the TGA and the NIIM HREC.

**5. NIIM Authorised Prescriber Application Form-Psychedelic Medicines: Required Evidence**

There are two separate application forms for psychedelic medicines, one for MDMA and one for psilocybin. The applicant must complete the appropriate application form(s) and provide the required evidence set out in the application form(s).

**5.1 Practitioner Eligibility Evidence**

The applicant must:

1. Be currently registered as a psychiatrist under the Australian Health Practitioner Regulation Agency (AHPRA);
2. Be a Fellow of the RANZCP as required by the TGA;
3. Supply evidence in support of their qualifications, knowledge, expertise and experience to use the unapproved good(s) and manage the condition for which it is prescribed. Demonstration of knowledge and expertise must include completion of a comprehensive course in PAT and/or other training in the use of the unapproved good(s). Training should include knowledge of the medical effects of MDMA and/or psilocybin (as appropriate), including potential adverse effects and training in practical aspects of delivering PAT, including the importance of maintaining professional boundaries and obtaining informed consent. Demonstration of experience in the use of the unapproved therapeutic good may include:
* prior experience in being involved in the treatment of a patient with PAT (using the same psychedelic medicine as that for which the authorised prescriber application is being made) under supervision or alongside another psychiatrist who is an Authorised Prescriber, in the context of the supervising psychiatrist’s private or public practice
* prior experience in treating a patient with PAT as part of a clinical trial (note: such training should include all aspects of PAT ie. preparation, dosing and integration). It may also include prior experience in treating a patient with PAT as part of a clinical trial (where the applicant was involved in all aspects of PAT ie. preparation, dosing and integration).

Evidence of experience may include a letter from the supervising psychiatrist or chief investigator of a clinical trial. The resume of the applicant must be appended to the application.

1. Hold medical indemnity insurance relevant to the practise of PAT and use of the psychedelic medicines

**5.2 Ancillary PAT Staff Qualifications, Training and Experience**

a. All ancillary PAT therapists involved in the delivery of a PAT treatment protocol, in addition to the Authorised Prescriber, must be trained in PAT.

b. The application should include detail of all therapists who will be involved in PAT treatments, including their names, minimum qualifications, relevant clinical experience and training in PAT. The authorised prescriber application also requires the applicant to submit the resumes of ancillary PAT therapists.

c. The application should clearly state the name, qualifications and AHPRA registration number of the medical practitioner who will be present and/or available on site at the treatment location on day(s) of dosing of the psychedelic medicine to handle any medical emergency that may occur. This may be the Authorised Prescriber themselves.

d. The roles of the Authorised Prescriber and other ancillary PAT therapists involved in the PAT treatment protocol should be clearly set out in the application and in the treatment protocol. The application and treatment protocol should clearly specify which therapists will be present with the patient during the dosing sessions(s), including who is the lead therapist and who is the secondary therapist.

e. The Lead PAT therapist is expected to be appropriately qualified in mental health, including treatment of the mental health condition for which the psychedelic medicine is indicated. The minimum qualification expected for a Lead PAT Therapist is that of a clinical psychologist or the equivalent. Note that a psychiatrist may also be the Lead PAT Therapist.
The Lead PAT therapist is expected to have clinical experience in PAT therapy involving the psychedelic medicine for which the authorised prescriber application is made. Experience may include:

* conducting PAT under supervision or alongside another psychologist who is experienced in treating patients with PAT as a Lead Therapist (using the same psychedelic medicine as that for which the Authorised Prescriber application is being made)
* involvement in a clinical trial into PAT as a therapist (using the same psychedelic medicine as that for which the Authorised Prescriber application is being made).

Evidence of experience may include a letter from the supervising psychologist or a letter from the chief investigator of a clinical trial.

f. Secondary PAT therapists involved in delivery of the PAT protocol are expected to be appropriately qualified and trained in PAT. The secondary PAT therapist is to either have experience in delivery of PAT or if not, work under the supervision of the Lead Therapist (who is experienced in delivery of PAT using the same psychedelic medicine as that for which the Authorised Prescriber application is made). Experience may also include involvement in a clinical trial into PAT as a therapist (using the same psychedelic medicine as that for which the Authorised Prescriber application is being made). Evidence of experience may include a letter from the supervising psychologist or a letter from the chief investigator of a clinical trial.

g. At least one member of the PAT dyad (pair) present during dosing session(s) should be female.

h. Ancillary PAT therapists are expected to be AHPRA-registered and/or belong to a relevant professional association. At least one of the treatment dyad of therapists involved during the dosing session(s) must be AHPRA-registered.

i. All ancillary PAT therapy clinician are expected to be of good professional standing.

j. All ancillary PAT therapy clinicians must hold professional medical indemnity insurance in relation to the practice of PAT.

h. The Authorised Prescriber and all ancillary PAT clinicians should undertake regular professional supervision with a clinician experienced in PAT involving the same psychedelic medicine as that for which the Authorised Prescriber application is being made.

**5.3 Clinical Justification for Use of the Unapproved Good(s)**

a. The applicant must provide a clinical justification for use of the unapproved product including evidence of the unapproved good’s suitability for the intended application, efficacy, expected benefits, any potential or expected adverse events including known risks and safety issues. Sources of evidence to support the use of the unapproved good include published systematic reviews, randomised controlled trials, cohort studies, case-control studies, case studies and so on, and should be appropriately referenced.

**5.4 Unapproved Product Details**

The application should include specific details of the unapproved product including:

* Trade name of product
* Active ingredient including strength
* Dosage form
* Sponsor details

Manufacturer details Note that only pharmaceutical grade products manufactured in accordance with Good Manufacturing Practice (GMP) will be approved. Extemporaneously compounded products or illicit forms of psilocybin or MDMA or mushrooms or their extracts known to contain psilocybin are not permitted to be prescribed or used.

**5.5 Clinical Treatment Protocol**

According to the TGA Guidelines (*Access To MDMA (3,4-Methylenedioxy-Methamphetamine) And Psilocybin For Therapeutic Purposes. Information For Psychiatrist Prescribers Version 2.0, February 2023[[5]](#footnote-5))* the treatment of PTSD with MDMA and treatment-resistant depression with psilocybin is expected to be part of a treatment protocol involving the assessment and ongoing psycho-therapeutic management by the psychiatrist in an appropriate clinical setting. The use of psilocybin or MDMA must occur under supervision in an inpatient or day clinic setting; take-home doses may not be authorised (patients do not have access to psilocybin or MDMA at any other time other than at the time of asupervised dose).

a. The application must include a detailed clinical treatment protocol which should include information about:

* assessment of suitability of patient: patient selection and exclusion criteria
* process of gaining informed consent
* details of the setting for supervised administration of the unapproved good (eg. accredited facility, day hospital, inpatient setting or day clinic)
* dosage regimen
* how the use of the unapproved good will be combined with psychotherapy as part of psychedelic assisted psychotherapy (PAT), including the roles of any support staff/PAT therapists involved, proposed method of monitoring, safeguards in place during administration ongoing psychotherapeutic management by the psychiatrist before and after administration of the unapproved medicine, and proposed follow-up and ongoing care of patients
* how patient vulnerability will be assessed and managed
* how risks associated with the use of the unapproved good will be managed including mechanisms for the detection, monitoring and reporting of potential adverse events and availability of a medical practitioner on site to handle any potential medical emergency on the dosing session day(s)
* how data on patient outcomes, including adverse events, of PAT will be assessed and collected systematically and longitudinally

b. It is expected that treatment protocols are evidence-based, that is, based on established PAT protocols that have been used in Australia and internationally in clinical trials of MDMA and psilocybin, though it is recognised that there may also be variations in treatment protocols.

c. Treatment protocols should be appropriately referenced which means that in-text referencing is used and a complete reference list provided in the appendices of the treatment protocol, in accordance with established referencing systems (eg. APA, Harvard, Vancouver etc).

d. Treatment protocols should include explicit measurement of patient outcomes of the PAT treatment, using appropriate validated measurement tools at appropriate time-points.

**6. Application Process**

6.1 Applicants are required to complete the NIIM Application Form for Authorised Prescribing of Psilocybin and MDMA, available on the NIIM HREC website.

6.2 Applicants are required to complete an application checklist, available on the NIIM HREC website.

6.3 Applicants are required to submit the following to the HREC Secretary at aps@niim.com.au:

* Application Form, signed and dated
* Completed Application Checklist
* Supporting evidence

NIIM will invoice the applicant following submission of the application.

6.5 Applicants are required to disclose:

a. whether they have applied to another HREC for Authorised Prescriber approval for an unapproved good within the last 12 months and whether approval has been denied, and the grounds upon which this has been denied. Evidence submitted includes written communication from the other HREC to the applicant.

b. whether they have applied to the TGA for Authorised Prescriber approval for an unapproved good and whether approval was denied, and the basis upon which it was denied.

6.6 Where supporting information or evidence of payment of application fee has not been supplied, applications will not be considered.

**7. HREC Approval Process**

7.1 The NIIM HREC will evaluate a psychiatrist’s application to become an Authorised Prescriber of psilocybin and/or MDMA under the TGA Authorised Prescriber Scheme and either approve it or not approve it at the next available meeting.

7.2 Decisions by the NIIM HREC will be by majority vote.

7.3 Initial approval is for 12 months. Re-approval must be sought on a 12 monthly basis.

7.4 The NIIM HREC will communicate their decision within five (5) working days of the HREC meeting in writing, via email. The letter, signed by the Chair of the HREC, will form the evidence that the applicant is required to submit to the TGA to obtain final approval. The letter will state:

* The unapproved goods approved for use and dosage form
* Approved indication
* Approved class of patients
* Requirements for reporting
* The fact that this letter forms part of the TGA approvals process under the TGA’s Authorised Provider Scheme and that applicants are required to complete the TGA application process
* The fact that ongoing approval is contingent on submission of evidence of continuing professional development (CPD) in relation to the unapproved good eg. successful completion of an NIIM HREC-approved CPD course

7.5 Where the HREC decides not to approve an application, the letter will state:

* That authorisation has not been granted
* The reasons for the decision
* The process of appeal

7.6 Where the NIIM HREC decides not to approve an application, it will notify the TGA of its decision.

**8. Applicant Monitoring and Reporting Requirements**

8.1 Psilocybin and MDMA have not been evaluated for safety, quality and efficacy. For this reason, according to the TGA, they could pose unknown risks.

8.2 The NIIM HREC will monitor the psychiatrist’s use of the unapproved therapeutic good(s) to ensure continued approval is appropriate.

8.3 As required by the TGA, it is a condition of the Authorised Prescriber Scheme that authorised prescribers complete 6 monthly reports for the periods of 1 January to 30 June and 1 July to 31 December each year. Authorised prescribers are required to report the number of new patients commenced on treatment and the total number of patients treated during this (6 month) period. Reports can be submitted through the [SAS & Authorised Prescriber Online System.](https://compliance.health.gov.au/sas/) Information on using the online portal system to submit six monthly reports is found in the [Authorised Prescriber online system guidance](https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme-online-system-guidance).

The NIIM HREC also requires completion of a 6 monthly report using the NIIM 6 monthly reporting template. In addition, as for any drug, adverse reactions associated with the unapproved good(s) must be reported to the TGA with a copy submitted to the NIIM HREC.

8.4 As required by the TGA and as for any adverse event authorised prescribers must submit reports of any adverse events and product defects to the TGA within specified time periods. See the TGA website for ways to report adverse events and product defects: [Reporting adverse events](https://aems.tga.gov.au/).

A copy of the adverse event report should also be submitted to the NIIM HREC.

**9. Applicant Re-Approval**

9.1 Applicants who have gained approval from the NIIM HREC and TGA as an authorised prescriber of MDMA and/or psilocybin must apply for re-approval of their Authorised Prescriber status on a 12-monthly basis. Applicants must apply at least 4 weeks prior to expiry of their NIIM authorised prescriber approval date.

9.2 Applicants who have gained approval from the NIIM HREC must submit, on a 12 monthly basis, evidence of completion of continuing professional development (CPE) in relation to the unapproved good.

9.3 Ancillary PAT therapists delivering the psychotherapy component of the Authorised Prescriber’s PAT treatment protocol are expected to engage in ongoing supervision from a relevant expert, demonstrate fidelity to the model in which they have been trained, and participate in continuing professional education (CPE) relevant to the PAT treatment being delivered. Evidence of this will form part of the re-approval process.

9.4 The NIIM HREC will take into account evidence supplied in the 6 monthly reports in granting (or not) re-approval.

9.5 The NIIM HREC will consider any new information available to determine whether re-approval of a psychiatrist’s application to be an Authorised Prescriber is warranted.

9.6 In addition to the requirements for 12 monthly re-approval, at any time where a suitable good becomes available on the ARTG, the TGA advises that the medical practitioner should stop using the unapproved good. At the time that the medical practitioner becomes aware of an approved alternative available on the ARTG, and he/she believes there is good reason to continue using the unapproved good, the medical practitioner is required to submit a clinical justification to the NIIM HREC as to why he/she should be able to continue using the unapproved good. This application should be made in writing to the HREC. The HREC will consider all evidence supplied and follow the processes set out in Section 7. Following re-approval by the HREC, the applicant must then submit a letter from the NIIM HREC as part of a new application to become an Authorised Prescriber.

**10. Revoking Authorisation**

10.1 The NIIM HREC may revoke an Authorised Prescriber approval if:

* A suitable alternative good becomes available and is entered on the Australian Register of Therapeutic Goods
* The HREC becomes aware of any significant concerns about the good’s safety
* The HREC becomes aware of any significant concerns about the psychiatrist’s prescribing practice in relation to the good
* The applicant fails to provide 6 monthly reports to the HREC and the TGA
* The applicant fails to supply evidence in relation to Applicant Re-approval
* The application does not meet any conditions that have been applied to the NIIM HREC’s approval or re-approval or the TGA’s approval or re-approval

**11. Appeals Against HREC Decisions**

11.1 Applicants who are dissatisfied with a HREC decision in relation to an Authorised Prescriber application may appeal in writing to the Director of NIIM. The applicant must detail reasons why he/she is appealing the decision.

11.2 The NIIM Director or their delegate will consider the evidence provided by the HREC and the applicant’s rationale for appeal.

11.3 The NIIM Director or their delegate will decide to either uphold the appeal or reject the appeal.

11.4 The outcome of the decision will be communicated to the applicant within 10 working days of receipt of their written appeal.

11.5 No further internal appeal process is available. Where an applicant remains dissatisfied with the decision, they may appeal to the relevant state and territory Ombudsman.

**12. Approvals Summary**

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| Policy/Procedure Code & Name | *NIIM HREC* *Authorised Prescriber Scheme (Psychedelic Medicines) Application Approval Procedures* |
| This Version Number and Date | V3.0, 6 August2024 |
| Date of Original Version | 6 June 2023 |
| Approving Authority | NIIM HREC |
| Approval Date for this version | 6 August 2024 |
| Next Review Date | 20 December 2025 |
| Contact Officer | NIIM HREC Chairperson |

1. RANZCP CM PPR Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression, available at: [www.ranzcp.org/getmedia/0cf57ea2-0bd7-4883-9155-d2ba1958df86/cm-therapeutic-use-of-mdma-for-ptsd-and-psilocybin-for-treatment-resistant-depression.pdf](http://www.ranzcp.org/getmedia/0cf57ea2-0bd7-4883-9155-d2ba1958df86/cm-therapeutic-use-of-mdma-for-ptsd-and-psilocybin-for-treatment-resistant-depression.pdf) [↑](#footnote-ref-1)
2. <https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme> [accessed 14 May 2023] [↑](#footnote-ref-2)
3. <https://www.tga.gov.au/resources/resource/guidance/access-mdma-34-methylenedioxy-methamphetamine-and-psilocybin-therapeutic-purposes-information-psychiatrist-prescribers> [accessed 14 May 2023] [↑](#footnote-ref-3)
4. RANZCP CM PPR Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression, available at: [www.ranzcp.org/getmedia/0cf57ea2-0bd7-4883-9155-d2ba1958df86/cm-therapeutic-use-of-mdma-for-ptsd-and-psilocybin-for-treatment-resistant-depression.pdf](http://www.ranzcp.org/getmedia/0cf57ea2-0bd7-4883-9155-d2ba1958df86/cm-therapeutic-use-of-mdma-for-ptsd-and-psilocybin-for-treatment-resistant-depression.pdf) [↑](#footnote-ref-4)
5. <https://www.tga.gov.au/resources/resource/guidance/access-mdma-34-methylenedioxy-methamphetamine-and-psilocybin-therapeutic-purposes-information-psychiatrist-prescribers> [accessed 14 May 2023] [↑](#footnote-ref-5)