**NIIM HREC AUTHORISED PRESCRIBER SCHEME APPLICATION FORM PSYCHEDELIC MEDICINES - PSILOCYBIN**

**CHECKLIST**

To assist with our processing of your application:

1. Please submit distinct documents as separate files, rather than merged into one file.
2. Please name each file clearly: include the applicant’s name in the file name.

|  |  |
| --- | --- |
| 1. Application Form (form completed, signed, and dated)
 |  |
| 1. Resumes: applicant and all therapists involved in psychedelic-assisted therapy (PAT)
 |  |
| 1. Evidence of professional education in psilocybin and PAT: applicant and all support staff/therapists involved in psychedelic assisted therapy
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| 1. Evidence of experience in conduct of PAT with psilocybin (eg. letter from supervisor): Applicant and Lead Therapist(s)
 |  |
| 1. Treatment Protocol- psilocybin for treatment resistant depression (TRD)
 |  |
| 1. Patient Informed Consent Form- Psilocybin Treatment
 |  |
| 1. Evidence of other (non-NIIM) HREC AP approval \*
 |  |
| 1. **Invoicing Party Contact Details**

Contact Name - Company or Individual Name: Primary Person: Email: Address:ABN:Please wait for an invoice to be raised. An invoice will be raised after the application has been received. The invoice is due for payment within 7 days and must be paid prior to the approval letter being issued. |  |

\*if applicable

**NIIM HREC AUTHORISED PRESCRIBER SCHEME APPLICATION FORM PSYCHEDELIC MEDICINES- PSILOCYBIN**

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**THIS FORM**

This application form is to be used by registered psychiatrists applying to become Authorised Prescribers of psilocybin for treatment resistant depression (TRD).

Note that the TGA advises that ‘psychiatrists should also consider and discuss with their patients the suitability of medical treatment options that are TGA approved (ie. included on the Australian Register of Therapeutic Goods) before seeking to prescribe psilocybin or MDMA to them under the Authorised Prescriber scheme[[1]](#footnote-1)’.

The acronym ‘PAT’ will be used to mean psychedelic-assisted therapy/therapies (PAT) throughout this document. PAT is 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’[[2]](#footnote-2).

**ABOUT THE AUTHORISED PRESCRIBER SCHEME**

In general, the Authorised Prescriber Scheme allows authorised medical practitioners to supply ‘unapproved therapeutic goods’, that is, medicines (or medical devices or biologicals) that are not included on the Australian Register of Therapeutic Goods, to a class of patients with a particular medical condition. However, only psychiatrists who are registered with the Australian Health Practitioner Regulation Agency (AHPRA) with a specialist registration in psychiatry and who have completed a Fellowship with the Royal Australian and New Zealand College of Psychiatrists (RANZCP) may apply to the TGA to become Authorised Prescribers of psilocybin and MDMA under the Standard Authorised Prescriber Pathway.

The Standard Authorised Prescriber (AP) pathway [[3]](#footnote-3) entails a 2-step application process:

* Step 1 is approval from a human research ethics committee (HREC). This must be obtained before applying to the TGA. **HREC approval is for 12 months**. Thereafter applicants must apply for renewal.
* Step 2 is the final approval from the TGA.

For guidance about the AP process and MDMA and psilocybin see the following TGA documents:

1. [Authorised Prescriber Scheme | Therapeutic Goods Administration (TGA)](https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme)

2. [access\_to\_mdma\_34-methylenedioxy-methamphetamine\_and\_psilocybin\_for\_therapeutic\_purposes.docx (live.com)](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.tga.gov.au%2Fsites%2Fdefault%2Ffiles%2F2023-02%2Faccess_to_mdma_34-methylenedioxy-methamphetamine_and_psilocybin_for_therapeutic_purposes.docx&wdOrigin=BROWSELINK)

Note also that since drugs and poisons legislation is state and territory-based, states and territories decide whether to give effect to the recommended changes in the Poisons Standards. It is possible that some states and territories may decide not to adopt amendments to the Poisons Standards. In some states and territories it may be an offence to supply, use or possess psilocybin and/or MDMA due to their classification in state and territory legislation as drugs of dependence, dangerous drugs or prohibited drugs, even when contained in Schedule 8 of the national Poisons Standard. It is therefore incumbent on practitioners seeking to apply to become authorised prescribers of psilocybin for treatment-resistant depression or MDMA for PTSD to understand the relevant state and territory drugs and poisons legislation in relation to these.

**SECTION 1: THE PRESCRIBER**

|  |  |  |
| --- | --- | --- |
| **A.** | **Applicant Name:**  |  |
| **B.** | **AHPRA No.:** |  |
| **C.** | **RANZCP Fellowship No.:** |  |
| **D.** | **Practice Address:**  |  |
| **E.** | **Phone Number:**  |  |
| **F.** | **Email:** |  |
| **G.** | **Third-Party Contact:**If the applicant is being supported by a third party, to be copied in on correspondence, please include contact information here including email*.* |  |
| **H.** | **Treatment Sites**For all sites at which the unapproved therapeutic good(s) will be prescribed and the treatment protocol conducted, provide the type of facility (eg. hospital inpatient dept, hospital outpatient dept, medical clinic) and full addresses. | **Site 1**Type of Facility:Address of Facility:**Site 2** Type of Facility:Address of Facility:**Site 3** Type of Facility:Address of Facility: |
| **I.** | **Applicant’s Qualifications, Expertise and Experience in Managing the Medical Condition for Which the Unapproved Therapeutic Good Will Be Used** Please provide details of your qualifications, expertise and experience in managing the medical condition for which the unapproved therapeutic good(s) will be used. | **Treatment Resistant Depression (Psilocybin):**  |
| **J.** | **Applicant’s Training in Psychedelic Medicines/Psychedelic-Assisted Therapy**Please provide details of your training in prescribing of psilocybin and PAT.***Please attach supporting evidence of your training in prescribing of psilocybin eg. certificate of completion of training/course*** |  |
| **K.**  | **Applicant’s Experience in Treating at Least One Patient with Psychedelic-Assisted Therapy utilising psilocybin**Eg. evidence of treating a patient with PAT involving the unapproved therapeutic good under supervision of a registered psychiatrist in Australia or New Zealand with experience in PAT; or letter from Chief Investigator of a clinical trial attesting to your experience in treating a patient with the unapproved good within a clinical trial setting  |  |
| **L.** | **Psychedelic-Assisted Therapies (PAT) Team/Ancillary PAT Therapists: Names, Roles, Qualifications, Training and Experience\*\***List the personnel (names), roles within the PAT Treatment Protocol (eg. Lead Therapist, Secondary Therapist), minimum qualifications, relevant experience of other professionals who will be involved in the PAT treatment of patients with the unapproved therapeutic good(s) and for the Lead Therapist, their clinical experience in PAT involving the unapproved therapeutic good (psilocybin). For each of the roles, provide details of:a) Relevant minimum professional qualifications; b) Relevant clinical experience in treatment of the relevant condition (TRD) including, where relevant, experience in PAT treatment using psilocybin; and c) Training in psychedelic-assisted therapy (PAT) including the use of psilocybin within the context of PATd) For the Lead Therapist(s), experience in PAT where psilocybin is utilised eg. letter from a supervisor who is appropriately qualified and trained in PAT e) Proposed supervision (eg. peer supervision) of PAT staff who will be involved in therapy dyads ***\*\*Note: Applicants MUST append the resumes of ALL support staff (PAT Team) involved in the treatment of patients using psychedelic assisted therapy (PAT), plus evidence of the support staff training in PAT eg. certificate of completion of PAT course, and in the case of the Lead Therapist, also evidence of experience in conduct of PAT where psilocybin is utilised*** | **Name:****Role in PAT Team and Delivery of PAT Treatment Protocol: Lead Therapist**Qualifications:Relevant Clinical Experience in TRD:Training in PAT including use of psilocybin within context of PAT:Relevant Clinical Experience in PAT (Lead Therapist):AHPRA-number:Professional Association: [Add more entries as required]**Name:** **Role in PAT Team and Delivery of PAT Treatment Protocol:**Qualifications:Relevant Clinical Experience in TRD:Training in PAT including use of psilocybin within context of PAT:Any Relevant Clinical Experience in PAT:AHPRA-number:Professional Association: **Name:****Role in PAT Team and Delivery of PAT Treatment Protocol:**Qualifications:Relevant Clinical Experience in TRD:Training in PAT including use of psilocybin within context of PAT:Any Relevant Clinical Experience in PAT:AHPRA-number:Professional Association: [Add more entries as required] |
| **M** | **Composition of PAT Therapist Team on Dosing Session Day(s)**Please indicate the composition of PAT staff present in the treatment/therapy room with the patient during the dosing session(s) (eg. two PAT therapists, one lead therapist/one secondary therapist and their names). Note that at least one of the therapists of the PAT dyad during the dosing session(s) must be female and one of the therapists must be AHPRA-registered.  |  |
| **N** | **Medical Practitioner on Site During Dosing Session Days**Name, qualifications and AHPRA number of medical practitioner who will be on site at the treatment location to handle any medical emergency on day(s) of dosing session(s) | **Name:****Qualification:****AHPRA number:** |

**SECTION 2: THE UNAPPROVED THERAPEUTIC GOOD(S): PSILOCYBIN FOR TREATMENT RESISTANT DEPRESSION (TRD)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Product Name (1)** | **Product Name (2)** | **Product Name (3)** |
| **A.** | **Product Trade Name** |  |  |  |
| **B.** | **Product Company** |  |  |  |
| **C.** | **Sponsor****Name & Address** |  |  |  |
| **D.** | **Manufacturer Name & Address** |  |  |  |
| **E.** | **Active Ingredient(s) and Concentrations** |  |  |  |
| **F.** | **Dosage Form (eg. tablet, capsule)** |  |  |  |
| **G.** | **Dosage or Dosage Range** (if applicable) |  |  |  |
| **H.** | **Expected Duration of Treatment** (eg. single dose given in 1 therapeutic session or single dose in more than one therapeutic session) |  |  |  |
| **I.** | **Overseas Regulatory Approval**Is this unapproved therapeutic good approved for the indication by an overseas regulatory body? If so, please list. |  |  |  |

Note that according to the TGA*: ‘It is best practice that the proposed treatment utilises pharmaceutical grade products that have been manufactured in accordance with Good Manufacturing Practice. Therefore neither “street” (illicit) psilocybin or MDMA nor mushrooms or their extracts known to contain psilocybin would be permitted for use’* ([access\_to\_mdma\_34-methylenedioxy-methamphetamine\_and\_psilocybin\_for\_therapeutic\_purposes.pdf (tga.gov.au)](https://www.tga.gov.au/sites/default/files/2023-02/access_to_mdma_34-methylenedioxy-methamphetamine_and_psilocybin_for_therapeutic_purposes.pdf)

**SECTION 3: CLINICAL JUSTIFICATION**

In this section you are required to provide a clinical justification for the use of the unapproved therapeutic good(s)/medicine. This should address expected benefits of the proposed unapproved medicine versus its potential risks.The application should contain appropriate sources of evidence to support the use of the ‘unapproved’ therapeutic good. Evidence can include: product information documents (or equivalent) (if the good is approved by an overseas regulator); randomised controlled trials; non-randomised controlled trial studies; individual case studies and consensus opinion of specialist colleges and societies. **NOTE:** This means that you should provide in-text referencing for any factual statements made in relation to your clinical justification in this section, and include a complete list of references either at the end of your submission or as footnotes. You may use any established referencing system eg. APA, Vancouver, Harvard.

|  |  |  |
| --- | --- | --- |
|  | **PSILOCYBIN FOR TRD** |  |
| **A.** | What evidence is there of the unapproved therapeutic good’s efficacy and expected benefits? Please provide details. |  |
| **B**. | Are there any expected adverse effects, risks and safety issues? Please provide details, including details of relevant toxicology associated with the unapproved therapeutic good. |  |
| **C.** | Is there an approved medicine (ie. contained in the ARTG) for the same indication as what you are applying to use the unapproved therapeutic good for? |  |
| **D.** | Have you already or will you attempt to use approved medicine(s) prior to supplying the unapproved therapeutic good? |  |
| **E.** | Why are approved medicines inappropriate or unsuitable for use? Why is the proposed unapproved therapeutic good a more appropriate option than an approved available alternative?  |  |

**SECTION 4: CLINICAL TREATMENT PROTOCOL**

In this section, you are asked to provide details of your treatment protocol for treatment resistant depression (TRD) with psilocybin. **Please ensure that you answer the questions within the text boxes and do not simply refer to the Treatment Protocol.**

Note that according to the TGA guidelines entitled *Access To MDMA (3,4-Methylenedioxy-Methamphetamine) And Psilocybin For Therapeutic Purposes. Information For Psychiatrist Prescribers Version 2.0, February 2023*[[4]](#footnote-4) the treatment of TRD 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 must occur under supervision in a medically controlled environment; take-home doses may not be authorised (patients do not have access to psilocybin at any other time other than at the time of asupervised dose).

**\*\*\*Note also** that communication with the TGA by the NIIM HREC indicates that treatment protocols are expected to be **evidence-based** and be consistent with treatment protocols used in clinical trials. **This means** **that you should provide in-text referencing and include a complete list of references either at the end of your submission or as footnotes. You may use any established referencing system eg. APA, Vancouver, Harvard.**

|  | **INDICATION: PSILOCYBIN FOR TREATMENT RESISTANT DEPRESSION (TRD)** |  |
| --- | --- | --- |
| **A.** | **Assessment of Suitability of Patient**Provide details of how you will assess the suitability of a patient to receive the unapproved therapeutic good, including the patient selection and exclusion criteria. Note that it is expected that this is conducted by the authorised prescriber and may not be delegated to any other individual. |  |
| **B.** | **Informed Consent**Provide details of the process of gaining informed consent from a patient to use the unapproved therapeutic good[[5]](#footnote-5). This should include informed consent for any type of therapeutic touch. It should also include specific mention of how any video digital recordings will be used as well as stored securely. ***Note: Please append a copy of your Informed Consent Form.***  |  |
| **C.** | **Treatment Setting**Provide details of the setting for supervised administration of the unapproved therapeutic good (eg. accredited facility, day hospital, inpatient setting, medical clinic) |  |
| **D.** | **Dosage Regimen**Provide details of the dosage regimen for the unapproved therapeutic good. Note that prescribing of psilocybin may not be delegated to any other individual and is the responsibility of the authorised prescriber.  |  |
| **E.** | **Summary of the Treatment Protocol** Please describe here in this application form **(do not just refer to the protocol)** how the use of the unapproved therapeutic good will be combined with psychotherapy as part of psychedelic assisted psychotherapy (PAT), including:a) the role of ancillary PAT Therapists involved, including who will be present with the patient at all times during the dosing session day(s) b) proposed method of monitoring immediate treatment response including safeguards in place during administration (this should include the details of a medical practitioner on site at the treatment location on the day(s) of dosing to handle any medical emergency that may occur);c) proposed method of monitoring treatment outcomes over time, including measurement of established clinical outcome variables using validated measurement tools and monitoring; d) ongoing psychotherapeutic management by the psychiatrist before and after administration of the unapproved therapeutic medicine including proposed follow-up and ongoing care of the patient***Note: Please append a copy of your documented Treatment Protocol\*\*\**** |  |
| **F.** | **Risks and Adverse Events**a) How will risks associated with the use of the unapproved therapeutic good be assessed (eg. potential adverse events to psilocybin, drug-drug interactions, patient vulnerability) and how will these be managed during the dosing session(s) as well as during other stages of PAT (ie. preparation and integration sessions)?b) How will any adverse events be managed and reported? |  |

**SECTION 5: DISCLOSURES AND UNDERTAKINGS**

5.1 I certify that I

[ ]  have not [ ]  have (tick one)

applied for Authorised Prescriber approval of another Australian HREC *(not NIIM)* within the last 12 months.

*Evidence: If yes, please append a copy of the letter from the other HREC and/or TGA*

Where an applicant has been refused approval for Authorised Prescriber by an Australian HREC or the TGA within the last 12 months, please detail why approval was denied.

|  |
| --- |
|  |

5.2 I understand that completing this application form is part of a two-step process to become an Authorised Prescriber and that if I am approved by the NIIM HREC, the next and final step is to apply to the TGA for final approval.

[ ]  Yes [ ]  No

5.3 I certify that any ancillary PAT Therapists (PAT Team) who will be involved in the treatment protocols detailed in this application are appropriately qualified, experienced and trained in relation to the unapproved therapeutic good(s) that are the subject of this application, as detailed in this application, and that they hold professional medical indemnity insurance relevant to the practice of PAT. I certify that at least one of the PAT therapist dyad/pair who will be present with the patient during dosing session(s) is AHPRA-registered.

[ ]  Yes [ ]  No

5.4 I understand that if any of the ancillary PAT Therapists (PAT Team) involved in the treatment of patients under my care using psychedelic-assisted therapy (PAT) change, I will notify the NIIM HREC and if required, the TGA, of any new support staff member’s name, qualifications, role in the PAT team, training in PAT and clinical experience. I also understand that the NIIM HREC may revoke my Authorised Provider approval if such individual(s) are deemed to not have the required qualifications, experience and training in PAT.

[ ]  Yes [ ]  No

5.5 I understand that my authorised prescriber approval is specific to the clinical sites listed in this application and that I am required to notify the HREC of any changes to sites from which psychedelic medicines/psychedelic-assisted therapies will be administered. I am aware that the HREC has the right to reject and/or cancel my authorised prescriber status if the facility in which I intend to practise psychedelic-assisted is not considered appropriate.

[ ]  Yes [ ]  No

5.6 I undertake to remain up to date in relation to knowledge about potential future approved goods that may be entered on the ARTG that could be used instead of the unapproved therapeutic good(s) to which this application relates, and where a suitable alternative good becomes available on the ARTG, I will stop using the unapproved therapeutic good, or where there is a good reason to continue using the unapproved therapeutic good, I will reapply for approval, submitting a clinical justification to the HREC on why I want to use the unapproved therapeutic good instead of the now-approved good.

[ ]  Yes [ ]  No

5.7 I understand that I am required to comply with all requirements of my state/territory in relation to the prescribing of psilocybin.

[ ]  Yes [ ]  No

5.8 I certify that in treating a patient with psychedelic-assisted therapies (PAT) using psilocybin, I have a therapeutic relationship with the patient, I will be directly responsible for the assessment of suitability for psilocybin and PAT, will discuss other therapeutic options with the patient, am directly responsible for the prescribing of the unapproved therapeutic good (psilocybin) and will not delegate this or the therapeutic assessment of the patient to any other individual.

[ ]  Yes [ ]  No

5.9 I certify that I hold professional medical indemnity insurance in relation to the practice of PAT and prescribing of the unapproved psychedelic medicine (psilocybin).

[ ]  Yes [ ]  No

5.10 I undertake to submit the required six-monthly reports to the TGA and the NIIM HREC.

[ ]  Yes [ ]  No

5.11 I agree to abide by any conditions set by the HREC and/or TGA in relation to approval to use the unapproved therapeutic good(s).

[ ]  Yes [ ]  No

5.12 I certify that I

[ ]  do not have a commercial interest in any of the products which I may prescribe.

[ ]  do have a commercial interest in one or more of the products which I may prescribe.

Details of my commercial interests and their management are as follows:

5.13 I certify that I understand that HREC approval is for 12 months only and that I will need to apply for renewal of my Authorised Prescriber approval at least 30 days before the expiry date.

[ ]  Yes [ ]  No

5.14 I certify that the information I have provided in this application is true and accurate.

[ ]  Yes [ ]  No

|  |  |
| --- | --- |
| **Full Name** |  |
| **Signature** |  |
| **Date** |  |

1. [access\_to\_mdma\_34-methylenedioxy-methamphetamine\_and\_psilocybin\_for\_therapeutic\_purposes.docx (live.com)](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.tga.gov.au%2Fsites%2Fdefault%2Ffiles%2F2023-02%2Faccess_to_mdma_34-methylenedioxy-methamphetamine_and_psilocybin_for_therapeutic_purposes.docx&wdOrigin=BROWSELINK) [↑](#footnote-ref-1)
2. 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-2)
3. [authorised-prescriber-scheme-221205.docx (live.com)](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.tga.gov.au%2Fsites%2Fdefault%2Ffiles%2F2022-12%2Fauthorised-prescriber-scheme-221205.docx&wdOrigin=BROWSELINK) [↑](#footnote-ref-3)
4. <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-4)
5. Note that according to the TGA, the Authorised Prescriber must advise patients that the TGA has not evaluated the ‘unapproved’ good’s safety, quality and efficacy; of the possible benefits and risks of its use; of the possibility that there may be unknown side effects; of any alternative approved goods. [↑](#footnote-ref-5)