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

**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
 |  |
| 1. Evidence of professional education in MDMA and PAT: applicant and all support staff/therapists involved in psychedelic assisted therapy
 |  |
| 1. Treatment Protocol- MDMA for PTSD
 |  |
| 1. Patient Informed Consent Form- MDMA 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- MDMA**

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**THIS FORM**

This application form is to be used by registered psychiatrists applying to become Authorised Prescribers of 3,4-methylenedioxy-methamphetamine (MDMA) for post-traumatic stress disorder (PTSD).

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.

**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 [[2]](#footnote-2) 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 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\*\*** Please provide details of your qualifications, expertise and experience in managing the medical condition for which the unapproved therapeutic good(s) will be used. | **PTSD (MDMA):**  |
| **J.** | **Applicant’s Training in Psychedelic Medicines/Psychedelic-Assisted Therapy**Please provide details of your training in prescribing of MDMA and PAT.***Please attach supporting evidence of your training in prescribing of MDMA eg. certificate of completion of training/course*** |  |
| **K.** | **Psychedelic-Assisted Therapy/Therapies (PAT) Team/ Support Staff: Names, Roles, Qualifications, Training and Experience\*\***List the personnel (names), roles, minimum qualifications and relevant experience of other professionals who will be involved in the treatment of patients with the unapproved therapeutic good(s). For each of the roles, provide details of:a) Relevant minimum professional qualifications; b) Relevant clinical experience in treatment of the relevant condition (PTSD) including, where relevant, experience in treatment using MDMA; and c) Training in the use of MDMA in the context of psychedelic-assisted therapy (PAT) that persons in these roles will have. ***\*\*Note: Applicants MUST append the resumes of ALL support staff involved in the treatment of patients using psychedelic assisted therapy (PAT), plus evidence of the support staff training in PAT.*** | **Name:****Role in PAT Team:**Minimum Qualifications:Relevant Clinical Experience:Training in use of MDMA in context of PAT:**Name:** **Role in PAT Team:**Minimum Qualifications:Relevant Clinical Experience:Training in use of MDMA in context of PAT:**Name:****Role in PAT Team:**Minimum Qualifications:Relevant Clinical Experience:Training in use of MDMA in context of PAT:[Add more entries as required] |

**SECTION 2: THE UNAPPROVED THERAPEUTIC GOOD(S): MDMA FOR PTSD**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **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). 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. 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.

|  |  |  |
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|  | **MDMA FOR PTSD** |  |
| **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 medicine for? |  |
| **D.** | Have you already or will you attempt to use approved medicine(s) prior to supplying the unapproved medicine? |  |
| **E.** | Why is the approved medicine inappropriate or unsuitable for use? Why is the proposed unapproved medicine 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 PTSD with MDMA.

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*[[3]](#footnote-3) the treatment of PTSD with MDMA 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 MDMA must occur under supervision in a medically controlled environment; take-home doses may not be authorised (patients do not have access to MDMA 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: MDMA FOR PTSD** |  |
| --- | --- | --- |
| **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 |  |
| **B.** | **Informed Consent**Provide details of the process of gaining informed consent from a patient to use the unapproved therapeutic good[[4]](#footnote-4).**Note: Please append a copy of your Informed Consent Form.**  |  |
| **C.** | **Treatment Setting**Provide details of the setting for supervised administration of the unapproved good (eg. accredited facility, day hospital, inpatient setting, medical clinic) |  |
| **D.** | **Dosage Regimen**Provide details of the dosage regimen for the unapproved therapeutic good |  |
| **E.** | **Summary of the Treatment Protocol** Please describe how the use of the unapproved therapeutic good will be combined with psychotherapy as part of psychedelic assisted psychotherapy, including:a) the role of any support staff involved; b) proposed method of monitoring treatment response including safeguards in place during administration;c) 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 and managed? (eg. patient vulnerability) 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.

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|  |

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 Support Staff 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.

[ ]  Yes [ ]  No

5.4 I understand that if any of the support staff/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 MDMA.

[ ]  Yes [ ]  No

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

[ ]  Yes [ ]  No

5.9 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

5.10 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:

5.11 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

5.12 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. [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-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. 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-4)