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

**1. Policy Statement**

The aim of this policy is to set out the principles by which the NIIM Human Research Ethics Committee (HREC) will receive and where appropriate approve applications from registered psychiatrists to prescribe psychedelic medicines as unapproved therapeutic goods under the Therapeutic Goods Administration’s (TGA’s) Authorised Prescriber Scheme. 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 Procedures are the *NIIM HREC* *Authorised Prescriber Scheme (Psychedelic Medicines) Application Approval Procedures.*

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. Application**

This policy and its related procedures apply only to applications by registered Australian psychiatrists who are Fellows of the Royal Australian and New Zealand College of Psychiatry (RANZCP) wishing to apply under the TGA’s Authorised Prescriber Scheme to be able to prescribe psilocybin and MDMA which are unapproved Schedule 8 (Controlled Drugs) therapeutic goods (unapproved goods are those not listed on the Australian Register of 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.

**HREC** Human Research Ethics Committee

**MDMA** 3,4‑methylenedioxy‑methamphetamine

**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)

**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. Principles**

4.1 Under the provisions of the Therapeutic Goods Act, the Therapeutic Goods Administration (TGA) administers a number of mechanisms to enable access to therapeutic goods which are not registered on the ARTG, referred to as ‘unapproved’ therapeutic goods.

4.2 In relation to MDMA and psilocybin, the TGA’s Authorised Prescriber Scheme provides a mechanism by which registered psychiatrists who are Fellows of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) can legally supply psilocybin for the treatment of treatment-resistant depression (only) and MDMA for the for the treatment of post-traumatic stress disorder (PTSD) (only).

4.2 Effective 1 July 2023, the TGA rescheduled psilocybin for the treatment of treatment-resistant depression, and MDMA for the treatment of PTSD to Schedule 8 (Controlled Drugs) within the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, also known as the Poisons Standard). However, access to these substances is restricted through new entries in Appendix D of the Poisons Standard, only permitting access to the substances under Schedule 8 as follows:

* + *‘authorisation to prescribe the substances for the above conditions will be restricted to registered psychiatrists who have obtained approval from a Human Research Ethics Committee (HREC), and have also been authorised by the TGA to be an Authorised Prescriber under the Authorised Prescriber Scheme*
  + *possession of the substances without authority will be illegal (for example, possession other than in accordance with a legal prescription). Note, however that it is not anticipated at this time that approval would be granted for protocols which enable the patient to be dispensed medicines containing these substances to take home’* *2*

Note that according to the TGA*: ‘Access restrictions remain in place for all indications for psilocybin and MDMA other than treatment-resistant depression and post-traumatic stress disorder respectively. For other indications these will remain as prohibited substances and remain in Schedule 9 of the Poisons Standard, limiting their use to medical and scientific research, such as clinical trials’2.*

*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.*

4.3 The TGA provides final approval for a registered psychiatrist to be an Authorised Prescriber of psilocybin and/or MDMA. The TGA’s mechanism for approval includes approval or endorsement of a registered psychiatrist’s application by a human research ethics committee (HREC), *prior* to final approval by the TGA.

4.5 The TGA provides guidance to medical practitioners, HRECs, Specialist Colleges and Sponsors with respect to roles and responsibilities and processes to be followed by each party in relation to applications to become an Authorised Prescriber, set out at: <https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme>.

The TGA also provides guidance to psychiatrists about the prescribing of psilocybin and MDMA, set out at: <https://www.tga.gov.au/resources/resource/guidance/access-mdma-34-methylenedioxy-methamphetamine-and-psilocybin-therapeutic-purposes-information-psychiatrist-prescribers> .

These guidance documents form the basis of the NIIM HREC’s approval criteria and procedures for applications from registered psychiatrists to become Authorised Prescribers of psilocybin for the treatment of treatment-resistant depression and MDMA for the treatment of PTSD under the TGA’s Authorised Prescriber Scheme.

4.6 The Royal Australian and New Zealand College of Psychiatrists (RANZCP) also provides guidance to its members on the therapeutic use of psychedelic medicines, set out in the following clinical memoranda(CM):

* CM: Therapeutic use of psychedelic substances, available at: [www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/therapeutic-use-of-psychedelic-substances](http://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/therapeutic-use-of-psychedelic-substances)
* 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)

These guidance documents are also taken into account in the development of NIIM HREC’s approval criteria and procedures for applications from registered psychiatrists to become Authorised Prescribers of psilocybin for the treatment of treatment-resistant depression and MDMA for the treatment of PTSD under the TGA’s Authorised Prescriber Scheme.

**5. Approval Criteria**

5.1 Approval criteria is based on the requirements set out in the *NIIM HREC* *TGA Psychedelic Medicines Authorised Prescriber Scheme Application Approval Procedures,* based on requirements set out in theTGA documents below, also taking into account key points from the RANZCP’s Clinical Memorandum on Therapeutic Use of Psychedelic Medicines[[5]](#footnote-5) and Clinical Memorandum PPR Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression[[6]](#footnote-6):

* *Authorised Prescriber Scheme. Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors Version 5.2 (December 2022)1*, or any later version, and;
* *Access To MDMA (3,4-Methylenedioxy-Methamphetamine) And Psilocybin For Therapeutic Purposes. Information For Psychiatrist Prescribers Version 2.0, February 2023 2,* or any later version published by the TGA.

**6. Roles and Responsibilities of the HREC**

6.1 The NIIM HREC will evaluate a registered psychiatrist’s application to become an Authorised Prescriber of psilocybin for the treatment of treatment-resistant depression and MDMA for the treatment of PTSD under the TGA Authorised Prescriber Scheme and either approve it or not approve it.

6.2 The NIIM HREC will provide written communication to the registered psychiatrist on the outcome of the application in a timely manner.

6.3 The NIIM HREC will monitor the registered psychiatrist’s use of the unapproved therapeutic goods via 6 monthly reporting*.*

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

6.5 The NIIM HREC has the right to 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 unapproved goods’ safety
* The HREC becomes aware of any significant concerns about the registered psychiatrists’ prescribing practice in relation to the unapproved good (s)
* The applicant fails to fulfil the requirements of approval as set out in the related Procedures
* The application does not meet any conditions that have been applied to the NIIM HREC’s approval or the TGA’s approval

**7. Roles and Responsibilities of the Authorised Prescriber**

7.1 A registered psychiatrist who wishes to apply to the NIIM HREC for approval as an Authorised Prescriber of psilocybin for the treatment of treatment-resistant depression and MDMA for the treatment of PTSD as part of the TGA Authorised Provider Scheme is required to follow the processes set out in the Procedures related to this policy.

7.2 A registered psychiatrist granted approval of his/her application to become an Authorised Prescriber of an unapproved therapeutic good by the HREC and the TGA must abide by the requirements set out in the Procedures related to this Policy, and requirements set by the TGA. This includes:

1. Remaining informed about changes to the benefits and risks of the unapproved good(s) as they arise;
2. Considering the benefits and risks the unapproved good may offer each patient it is prescribed for;
3. Obtaining written informed consent from each patient before prescribing;
4. Arranging the supply of the goods directly through a pharmacy;
5. Monitoring the patient during and after the use of the unapproved good;
6. Informing the TGA and the NIIM HREC of any adverse events associated with the use of the unapproved good(s);
7. Complying with relevant State or Territory legislation governing the supply of unapproved therapeutic goods

7.3 Whilst it is recognised that psychedelic assisted therapy (PAT) is conducted by a therapeutic team that will include other appropriately qualified mental health practitioners, the Authorised Prescriber carries the overall responsibility for the course of PAT, including patient selection, detailed assessment, obtaining informed consent, monitoring outcomes and progress of the therapy, and patient follow-up after the completion of treatment.

**8. Appeals against HREC Decisions**

8.1 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. The Director of NIIM will consider the appeal in accordance with the related Procedures.

8.2 Where an applicant remains dissatisfied with the decision of the Director of NIIM, no further internal appeal process is available. Applicants may appeal to the relevant state and territory Ombudsman.

**9. Approvals Summary**

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| Policy/Procedure Code & Name | NIIM HREC Authorised Prescriber Scheme (Psychedelic Medicines) Application Approval Policy |
| This Version Number and Date | V 2.0, 20 December 2023 |
| Date of Original Version | 6 June 2023 |
| Approving Authority | NIIM HREC |
| Approval Date of this Version | 20 December 2023 |
| 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. [www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/therapeutic-use-of-psychedelic-substances](http://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/therapeutic-use-of-psychedelic-substances) [↑](#footnote-ref-5)
6. [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-6)