NSW Health

Application for Approval to Prescribe or Supply Psychedelics Psilocybine or MDMA [N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine] Schedule 8 Product for Human Therapeutic Use

as required under the Poisons and Therapeutic Goods Act 1966 (NSW)

This application is to be used for Schedule 8 substances:

- **psilocybine or MDMA [N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine]**

Only complete this application if you are a **psychiatrist**. All other prescribers please refer the patient to a psychiatrist for consideration of prescribing and supply of psilocybine for treatment resistant depression or MDMA for post-traumatic stress disorder.

Practitioners should have regard to the relevant diagnostic criteria set out in the International Statistical Classification of Diseases and Related Health Problems – 11th Revision (ICD-11) and the Diagnostic and Statistical Manual of the American Psychiatric Association – Fifth Edition (DSM-5).

Psilocybine and MDMA substances are to be administered under direct medical supervision, in an appropriately supervised healthcare setting with good clinical governance practices, established administration and patient monitoring procedures and protocols. This includes the ability to manage any behavioural and/or medical emergencies.

Australian Register of Therapeutic Goods (ARTG)

The NSW Ministry of Health recommends that preference be given to the use of medicines listed on the ARTG. Unregistered medicines have not been assessed by the Therapeutic Goods Administration (TGA) for safety or efficacy and should only be used when a suitable ARTG medicine is not available.

Before starting the application, please make sure you:

- **have authorisation from the Therapeutic Goods Administration (TGA) Authorised Prescriber Scheme (AP)**
- **have Human Research Ethics Committee (HREC) approval**
- **are part of a psychedelic psychotherapy treating team which consists of a medical practitioner and other Ahpra registered health practitioners**

CLINICAL ADVICE AND SUPPORT

The NSW Ministry of Health requires that your prescribing is in accordance with the AP approval issued to you, TGA Guidelines and the RANZCP guidance including the Clinical Memorandum: Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression.

The NSW Ministry of Health recommends the use of **SafeScript NSW** to assist practitioners to make informed clinical decisions https://www.health.nsw.gov.au/safescript Consider checking **SafeScript NSW** for evidence of alerts or other issues related to the prescribing or supply of high-risk monitored medicines.

The *Royal Australian and New Zealand College of Psychiatrists (RANZCP) psychedelic assisted therapy information hub* has a number of published resources and updates on the use of psilocybine and MDMA in Australia and can be accessed here: https://www.ranzcp.org/clinical-guidelines-publications/in-focus-topics/psychedelics.

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The NSW Ministry of Health requires that the applicant submits treatment and adverse event data at regular intervals as specified on the Psychedelic Assisted Therapy Data collection form: Treatment outcomes and adverse events

Applicants can find information on the TGA Authorised Prescriber Scheme at https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme.

Privacy Statement: *The information set out in this form is required by the NSW Ministry of Health for the issuance of an authority to prescribe or supply a Schedule 8 medicine as required under the law. The collection, use and disclosure of the information provided will be in accordance with privacy laws. Information collected as part of the application process may be used and disclosed as part of assessing the application. Medicare numbers may be used for the purpose of patient identification. Practitioner information, and data regarding the number of patients for whom they hold authorities to prescribe or supply a Schedule 8 medicine, may also be used and disclosed for policy and planning purposes. The information collected may be disclosed to health practitioners when necessary to facilitate coordination of treatment and patient safety or where required or authorised by law. The application may not be processed if all information and all declarations requested on the form are not completed. For further information on privacy, visit http://www.health.nsw.gov.au/patients/privacy*

☐ **I confirm that I have read and understood all the information above including 'Clinical Advice and Support' and the 'Privacy Statement'.**

(This declaration is mandatory and must be completed)

Enquiries:

Please direct any enquiries to the Pharmaceutical Services Unit:
Tel: **(02) 9424 5923**
email: MOH-S8Auth@health.nsw.gov.au

Submitting the application:

Fax completed form to the Pharmaceutical Services Unit:
Fax: **(02) 9424 5889** or
email to: MOH-S8Auth@health.nsw.gov.au

Processing Time:

Please allow up to **30 business days** for the processing of applications.

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NSW GOVERNMENT

SECTION A – PRESCRIBER DETAILS

Prescriber Name: (as displayed in AHPRA)

First Name (s): _____ Middle Name(s): _____

Family Name: _____

I have completed a Fellowship with the Royal Australian and New Zealand College of Psychiatrists (RANZCP)

☐ **Yes** ☐ **No**

Name of Practice: _____

Address: _____ Suburb/town: _____

Postcode: _____ Telephone: _____ Fax: _____

Mobile: _____

Email: _____ (please note this email address will be used for all correspondence)

AHPRA Registration No.: _____ PBS Prescriber No.: _____

SECTION B – PATIENT DETAILS

Patient Name: (as shown on Medicare card)

First Name: _____ Middle Name(s): _____

Family Name: _____

Patient also known as: (if applicable)

First Name: _____ Middle Name(s): _____

Family Name: _____

Address: _____ Suburb/town: _____

Postcode: _____ Medicare number (if applicable): _____ Ref no.: _____

DVA number (if applicable): _____

DOB: _____ (dd/mm/yyyy) Sex: ☐ Male ☐ Female ☐ Another term

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SECTION C – PRE-QUESTIONS

1. IS THE PATIENT CURRENTLY ENROLLED ON THE OPIOID TREATMENT PROGRAM (OTP)

☐ **No**. Go to question 2

☐ **Yes**. I am the authorised OTP prescriber. Go to question 2

☐ **Yes**. I am NOT the authorised OTP prescriber. **Has the patient been reviewed by the authorised OTP prescriber and written agreement to the proposed treatment obtained?**

- ☐ **Yes**. Go to question 2
- ☐ **No**. Contact the authorised OTP prescriber and obtain written agreement before submitting this application. **This application cannot proceed and will not be considered until written agreement is obtained.**

2. DO YOU CONSIDER THIS PATIENT TO BE DRUG DEPENDENT?

A 'drug dependent person' means a person who has acquired, as a result of repeated administration of:

(a) a drug of addiction, or

(b) a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985,

an overpowering desire for the continued administration of such a drug. (section 27 of the Poisons and Therapeutic Goods Act 1966).

☐ **Yes**.

☐ **No**.

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SECTION D – DRUG AUTHORISATION DETAILS

Schedule 8 substance(s): _____

Maximum dose of the Schedule 8 substance to be delivered per treatment session (mg): _____

Number of intended doses per treatment session: _____

Treatment interval between each dose (hours): _____

Maximum number of medication treatment sessions: _____

Interval between each medication treatment session (weeks): _____

This Product is a proprietary product being imported from overseas.

☐ **Yes**. Name of sponsor: _____

☐ **No**. Only pharmaceutical grade products can be used. Please contact Office of Drug Control for information on where to source the product. You must have a sponsor that will supply the substance before this application can proceed.

TGA Authorised Prescriber Scheme (AP) details

TGA AP approval number for the Schedule 8 substance, dosage form and indication:

_____

Date of TGA AP approval: _____

Expiry date of TGA AP approval: _____

Human Research Ethics Committee (HREC) details

Name of HREC: _____

HREC Reference number: _____

HREC approval valid from: _____ to _____

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SECTION E – INDICATIONS FOR PRESCRIBING

Clinical indication(s) for use:

☐ **Psilocybine for treatment resistant depression.**

- The patient has failed to receive satisfactory improvement for the major depressive episode despite the adequate trialling of at least 2 different classes of antidepressant medications, unless contraindicated, and:
  - the patient's adherence to antidepressant treatment has been formally assessed
  - the trialling of each antidepressant medication has been at the recommended therapeutic dose for a minimum of 3 weeks
  - where clinically appropriate, the treatment has been titrated to the maximum tolerated therapeutic dose
  - the patient will be assessed using a RANZCP recommended rating scale before the start of the psychedelic treatment course

☐ **MDMA for post-traumatic stress disorder**

- The patient has been assessed and has diagnostic features as per the DSM-5 or ICD-11 diagnostic requirements for Post traumatic stress disorder (PTSD)

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SECTION F – DECLARATION

I declare that:

- I have explained the following to the patient and obtained their informed consent:
  - where the product is unregistered, that it has not been assessed for safety or efficacy by the TGA
  - the nature of treatment and potential harms associated with the use of psychedelics and psychedelic assisted therapy specifically
- treatment will be delivered in accordance with the AP approval, TGA Guidelines and any RANZCP guidance including the Clinical Memorandum: Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression
- I have gained appropriate training to provide psychedelic assisted psychotherapy.
- The medicine will be administered under my direct supervision and I will remain present throughout the treatment session
- any supporting clinical therapists who form part of the psychotherapy treating team are appropriately trained and registered with Ahpra
- the treatment will be provided in an appropriately supervised healthcare setting where an environmental risk assessment has been conducted and incidents of behavioural and/or medical emergencies can be adequately managed
- I will submit treatment and adverse event data to NSW Health as required using the forms provided.

By signing below, I confirm the accuracy of this declaration and my commitment to uphold the standards expected in this capacity.

Signature: Print and Sign _____ Date: _____ (*dd/mm/yyyy*)