MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Application Form

Approval to Prescribe/Supply/Administer

Application for a New Approval (Psychedelic-assisted therapy)

Misuse of Drugs Regulations 1977

INFORMATION FOR APPLICANTS

- This form is used by a medical practitioner to make an application for approval to prescribe/supply/administer controlled drugs that require approval under regulation 22 Misuse of Drugs Regulations 1977, for psychedelic-assisted therapy outside of a research setting (for example psilocybin).
- The applicant must be the medical practitioner applying for approval to conduct the activities.
- For the application to be considered, all applicable sections of the application form must be completed, and the required supporting information attached.
- Before filling out this application you should make yourself familiar with the criteria Medsafe will use to assess the application. Guidance is available on the Medsafe website (https://medsafe.govt.nz/profs/psychedelics.asp).

APPLICATION FORM SUBMISSION

- This application form can be completed electronically using a pdf reader. The current version of Adobe Reader, available free of charge from the Adobe website (https://get.adobe.com/reader) is recommended.
- The completed application form should be submitted with any supporting documents, by the applicant, to Medsafe by email (medicinescontrol@health.govt.nz). A copy of the form should be retained for the applicant's records.

Section 1: Applicant

The Applicant is the medical practitioner completing this form, who is applying for the Approval.

1.1. Title:

1.2. First name:

1.3. Preferred name:

1.4. Surname:

Contact details

1.5. Email:

1.6. Phone:

Health practitioner registration details

1.7. HPI-CPN:

1.8. Does your annual practicing certificate (APC) include vocational scope(s)?

- [ ] No
- [ ] Yes, please specify:

Clinical expertise and training

1.9. Describe the clinical experience and training you hold that is applicable to the proposed use of the product:

Section 2: Product Details

2.1. This Application is being made to prescribe/supply/administer the following product(s):

Note: For each product please provide supporting documentation to demonstrate it is pharmaceutical grade (including, for example, a certificate of analysis).

Product	Component (e.g. psilocybin)	Strength	Form

2.2. Describe where the above product(s) are intended to be sourced from:

Section 3: Treatment Protocol

3.1. What is the indication the product(s) are proposed to be used for?

3.2. Provide supporting evidence/information to support use of the product(s) for the intended indication.

3.3. Provide a copy of the current treatment protocol.

Note: Refer to the published guidance for details of the assessment criteria

3.4. Describe where you will be administering and monitoring the treatment:

Section 4: Scientific Peer Review

4.1. Describe the scientific peer review activities that are implemented/proposed, and details of any support networks:

Note: Please provide any applicable supporting documentation, for example completed peer reviews.

Section 5: Declaration

5.1. Applicant declaration

I confirm that I:

1. Solemnly and sincerely declare that the statements made in this Application are true and correct; and
2. Agree to provide any further information as required by Medsafe to assess the application.

Date:

Note: To sign this document electronically apply a digital signature, or attach a signature image file, or use an on-screen signing function (for example 'Fill & Sign' in Adobe Reader). If completing the signature electronically is not possible, print the form and sign in pen.

Digital Signature *Click below to apply*		**Signature Image File** *Click below to attach*		**Signature** *Sign below*
	OR		**OR**	