Guidelines for applications for approval to prescribe psychedelics for psychedelic-assisted therapy

Version 1.0 (24 July 2025)

This guidance is provided to assist practitioners to apply for approval, under regulation 22 of the Misuse of Drugs Regulations 1977, to prescribe, supply and administer psychedelics such as psilocybin for a defined clinical purpose, outside of a research setting.

There are restrictions on the prescribing, supply and administration of certain controlled drugs that are specified by regulation 22 of the Misuse of Drugs Regulations 1977. Many psychedelics are classified as Class A or Class B1 controlled drugs in New Zealand, including psilocybin (Class A). The restrictions of regulation 22 apply to these psychedelics.

Applications

- Applications to prescribe, supply and administer these psychedelics for psychedelic-assisted therapy are administered by Medsafe.
- An application form is available on the website (https://medsafe.govt.nz/profs/psychedelics.asp).
- A medical practitioner intending to prescribe psychedelics for psychedelic-assisted therapy is expected to have a good knowledge and understanding of the medicines and the psychotherapeutic processes involved in psychedelic-assisted therapy. They should hold prior experience, such as involvement in prescribing the medicines in a research setting, or experience working in a collegial relationship in a relevant practice setting.
- The applicant is responsible for sourcing the medicine and for its quality, as at this time there are no approved products containing these psychedelic medicines in New Zealand. A Licence to Import Controlled Drugs may be required if the product is to be sourced from overseas (please contact Medsafe for guidance, email medicinescontrol@health.govt.nz).
- Applications should include a clinical treatment protocol that is maintained by the applicant, and supported by clinical research and independent scientific peer review.

Assessment criteria

Medsafe will assess an application against the following criteria, taking into consideration the medical practitioner, the product, the proposed treatment protocol and scientific peer review input.

1. Medical practitioner
1.1. The medical practitioner is registered with the Medical Council of New Zealand and holds a current Annual Practicing Certificate (APC) with an appropriate vocational scope.
1.2. The APC held by the medical practitioner does not include conditions that would affect the application.
1.3. The medical practitioner has appropriate clinical experience and training applicable to the proposed use of the product.

2. Product
2.1. The product is pharmaceutical grade (i.e. not mushrooms or non-pharmaceutical grade extracts).
2.2. The product is appropriately imported and/or manufactured, with the entities involved holding any required licences and/or authorisations.
3. Treatment protocol
3.1. There is a defined treatment protocol.
3.2. The medical practitioner will conduct administration and monitoring of the treatment in an appropriate supervised environment.
3.3. There is evidence to support the use of the product for the intended indication.
3.4. The protocol must contain reference to key aspects of use and monitoring of the product: • Specified indication • Participant selection details (including screening for eligibility, inclusion and exclusion criteria and the patient withdrawal process) • Consent process • Consideration of concomitant medications • The number of dose sessions required • Any rescue medications to be used • How efficacy will be assessed • Assessment of outcome measures • Follow up • Details of supporting clinical therapists
4. Scientific peer review
4.1. The medical practitioner has obtained scientific peer review of the proposed activities and has access to an appropriate support network.

Contact Medsafe

Medicines Control Branch (email medicinescontrol@health.govt.nz).