Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Checklist for prescribing psychiatrists of MDMA and psilocybine

This checklist summarises requirements for psychiatrists applying to access MDMA and psilocybine under the Authorised Prescriber (AP) scheme for psychedelic-assisted psychotherapy (PAT/PAP). Full details available at Accessing MDMA and psilocybine as a psychiatrist and Authorised Prescriber Scheme.

1	Registration as a specialist psychiatrist	Check
	Proof of registration as a specialist psychiatrist with the Medical Board of Australia (e.g. Ahpra registration number MED0000123456)	☐
2	**Clinical treatment protocol** **AP must explicitly name and version all updated protocols, ensuring each revision is clearly distinguishable to facilitate efficient updates and document control.**	**Check**
	A. Medical practitioner training and experience The psychiatrist must demonstrate experience in psychedelic-assisted psychotherapy through • prior experience with a clinical trial involving psychedelics **or** • provide evidence of structured supervision by another experienced AP psychiatrist. Psychiatrists should refer to appropriate guidance from the Royal Australian and New Zealand College of Psychiatrists (RANZCP) regarding specific supervision and supervisor experience criteria.	☐
	B. Treatment site/s The AP psychiatrist is responsible for ensuring their selected site(s) meet the following requirements: • Equipment and trained staff for clinical care, monitoring, medical/behavioural emergencies and emergency resuscitation • Secure storage and record keeping for Schedule 8 medicines • Ability to address adverse events, with immediate access to rescue medications • Located near (within 15 minutes of) accredited healthcare facility with an emergency department • Clear documentation treatment plans, consent, adverse events • Adheres to all state/territory requirements	☐

	C. Clinical justification and evidence for use of the unapproved product
	• Provide a clear clinical justification for the use of the product, including:
	  ○ Reasons for use instead of products included in the ARTG
	  ○ Treatment will only be offered to patients who have unsuccessfully trialled ARTG products for the indication
	  ○ Treatments trialled and how many (e.g. **≥2** pharmacological and relevant non-pharmacological)
	  ○ Declaration that you will discuss the suitability of treatment options included in the ARTG with the patient
	• Provide clinical studies demonstrating the efficacy and safety of the product for the indication (list **recent** peer-reviewed, published randomised controlled trials)
		☐

	D. Product details • Active ingredient, strength (stated on product label), dosage form (e.g. capsule), trade name, manufacturer and sponsor details, product information leaflet (if available) **Logistics arrangements**	☐

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Reference/Publication #

	• Importation arrangements, • Pharmacy supply (name, location/proximity to the treatment site, dispensing/delivery arrangement), storage arrangements, handling/administration • Declare compliance with state and territory regulatory frameworks for psychedelic medicines. **Quality requirements** • Declare product complies with Therapeutic Goods Order (TGO) 112 or 113 • Declare product is manufactured in accordance with the relevant principles of good manufacturing practice (GMP)	
	E: Use and monitoring • Description of indication, • Management of concomitant medications, • Dosing approach (dose to be administered, number of dosing sessions, interval), • Monitoring protocol (vital signs, anxiety, mental state), • Safety measurements, rescue medications and use, • Efficacy/outcome measures, how completion of therapy will be determined, • Process for long-term follow-up (registry or outsourced use is permitted with consent). *RANZCP provides suggested assessment scales. Justify use of other scales*	☐
	F: Efficacy and safety Detail the product's efficacy and expected benefits. Include: • known/expected adverse effects and • risks and their management (managing anxiety and vulnerability, safety measures, toxicology)	☐
	G: Participant selection and withdrawal *The psychiatrist is responsible for conducting patient screening.* • Where non-face-to-face consultation for screening is proposed, this should be clearly justified, and in line with Ahpra recommendations. • Describe the screening and baseline assessment process for eligibility • List inclusion and exclusion criteria • Outline a clear withdrawal process for patients and include a statement in the consent form.	☐
	H: Consent process *The psychiatrist is responsible for conducting initial and ongoing informed consent.* Provide a clear description of the informed consent process. Patient information and consent form must include (but not limited to): • Purpose of treatment and what participation involves • Risks associated with the medicine and risks during dosing sessions • A financial consent statement • Declaration the product is unapproved e.g. "The product is unapproved and not included in the ARTG. I understand that the TGA has not assessed the quality, efficacy or safety of the product." • where in-person consent is not possible, it must meet equivalent standards of patient understanding and documentation. • Where sessions are to be video-recorded, this must be clearly specified and consent explicitly obtained and documented.	☐
	I: Psychotherapy and dosing sessions • Outline schedule of sessions (number of preparation, dosing, and integration sessions, intervals, format and structure) • Include a clear explanation of how each session will be conducted, including therapeutic approach, setting, and required personnel • Confirm the suitability, qualifications, competence and training of all therapists involved in care • Confirm patients will not have access to MDMA or psilocybine outside the supervised dosing sessions. All administration will occur under direct supervision of AP psychiatrist in line with safety and regulatory requirements	☐

	J: Supporting clinical therapists and oversight Identify the type of staff involved in each session and any supporting staff. Preferably the same therapists at each session. Dosing sessions should include TWO staff members. The psychedelic assisted psychotherapy dyad must include at least ONE therapist: • who holds general registration with a National Board, specifically the Psychology Board with endorsement as Clinical Psychologist, Medical, Nursing and Midwifery, **or** Occupational Therapy Boards of Australia; AND where the practitioner's scope of practice includes psychedelic-assisted psychotherapy. • That therapist must demonstrate appropriate skills, training and competence relevant to psychedelic assisted psychotherapy, as determined by the psychiatrist and subject to HREC oversight. • The AP psychiatrist is responsible for determining the qualifications and experience of any ADDITIONAL practitioners. • The therapy team must also be approved by the HREC. • Supporting therapists must be properly trained on evidence-informed protocols for PAT. **Authorised Prescriber oversight** • Declare the AP psychiatrist will be present in-person during the administration of the psychedelic (this does not need to be the full dosing day) • The AP psychiatrist is responsible for conducting patient screening and obtaining written informed consent • The AP psychiatrist is responsible for overall psychotherapeutic management of the patient	☐
3	**HREC approval**	
	Apply for approval from a HREC registered with the National Health and Medical Research Council (NHMRC) dated within the last three months. This approval must have at least 24 months until its expiry and be signed by the Chair. It should not be forward dated.	☐
4	**Submit an AP application**	
	Submit application through the SAS & Authorised Prescriber Online System Further information can be found in the SAS & Authorised Prescriber Scheme Online system guidance document ATTACH: HREC approval, clinical treatment protocol, patient information, consent forms and other supporting documents	☐
5	**Other considerations**	
	Sponsor supply Once approved, the AP psychiatrist or a pharmacist will need to contact a sponsor/supplier to arrange supply. The sponsor requires a copy of the TGA approval letter to release the stock.	☐
	Import permission Importers must obtain a licence and/or permission to import MDMA and psilocybine from the Office of Drug Control (ODC) prior to importing the product. ODC can be contacted at ncs@health.gov.au.	☐
	State/territory requirements State/territory departments should be contacted directly for further information on complying with all state/territory laws.	☐
	Patient reporting APs must report the number of patients treated to the TGA every 6 months (1 January to 30 June and 1 July to 31 December). Reports can be submitted using the SAS & AP Online System. See AP reporting user guide	☐
	Protocol amendments Prescribers must ensure amendments to the treatment protocol are approved by the HREC before they are submitted to the TGA for review. Once the TGA delegate confirms acceptance of the amendment, a confirmation email will be sent to the AP psychiatrist.	☐

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