Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Checklist for prescribing psychiatrists of MDMA and psilocybine

This checklist summarises key obligations for psychiatrists applying to access MDMA and psilocybine under the Authorised Prescriber (AP) scheme.

For full details of the Authorised Prescriber scheme requirements summarised in this document, please review the Authorised Prescriber Scheme guidance for medical practitioners and the Accessing MDMA (3,4-methylenedioxymethamphetamine) and psilocybine as a psychiatrist.

Note 1: This information is provided for guidance only and does not address every aspect of the relevant legislation. Independent legal advice should be sought to ensure that all legislative requirements are met.

Note 2: A separate Human Research Ethics Committee (HREC) and AP submission is required for MDMA and psilocybine.

1	Prescriber qualifications	Check
	Provide evidence you are registered as a specialist psychiatrist with the Medical Board of Australia.	☐
2	**Treatment protocol**	**Check**
	Treatment protocols are required for both the HREC application and the TGA Authorised Prescriber application. Aspects of the treatment protocol are likely to be very similar to the protocols that have been used in Australia and internationally in clinical trials of these substances. To include but not limited to:	
	(a) Medical practitioner details The psychiatrist should provide evidence of specific clinical experience and training applicable to the proposed use of the product.	☐
	(b) Practice location Evidence the psychiatrist will conduct administration and monitoring of the treatment in an appropriate supervised environment (i.e. accredited facility, either day hospital or inpatient setting).	☐
	(c) Clinical justification and evidence for use of the unapproved product (i) Consideration of Australian Register of Therapeutic Goods (ARTG) registered products: psychiatrists must specify that only patients who have unsuccessfully trialled ARTG registered products for the indication will be considered for treatment. (ii) Evidence: to support the use of the unapproved product for the intended indication along with sources of evidence to support the use of the unapproved good (i.e. RCTs).	☐

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	(d) Product Active ingredient, strength, dosage form, trade name, manufacturer/sponsor details. Access and storage. (i) Products other than pharmaceutical grade psilocybine and MDMA will not be approved by the TGA. (ii) Products manufactured at Good Manufacturing Practice (GMP) licenced sites strongly preferred. (iii) Declare products conform with the relevant Therapeutic Goods Order (see: Complying with the quality requirements for MDMA and psilocybine). (iv) Extracts of mushrooms will not be approved.	☐
	(e) Use and monitoring Definition of the specified indication, concomitant medications, number of dose sessions required, rescue medications, assessment of efficacy, assessment of outcome measures, completion of therapy and follow up.	☐
	(f) Efficacy and safety Any known/expected adverse effects, risks including but not limited to how patient vulnerability will be managed, safety measures and related toxicology.	☐
	(g) Participant selection Screening for eligibility, inclusion and exclusion criteria and patient withdrawal process.	☐
	(h) Consent process (please attach consent form with the clinical protocol) Details of the consent process, the purpose of the treatment and what is involved, the medical risks involved with the drug and in using an unapproved drug, psychological risks and physical risks during the session.	☐
	(i) Psychotherapy Psychoeducation and preparation for the dose sessions, anxiety management strategies, strategies to monitor mental state and wellbeing, supporting staff management.	☐
	(e) Supporting clinical therapists Supporting therapists are expected to be properly trained on evidence-informed protocols for psychedelic-assisted psychotherapy and should hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology or equivalent.	☐
3	**Obtain HREC approval**	**Check**
	Approval from a HREC registered with the National Health and Medical Research Council (NHMRC).	☐
4	**Submit an AP application**	**Check**
	(a) **HREC approval and clinical protocol** documentation are required for submission of the AP application.	☐
	(b) Submit application through the SAS & Authorised Prescriber Online System. Information on using the online portal system can be found in the SAS & Authorised Prescriber Scheme Online system guidance document.	☐
5	**Other considerations**	**Check**

	(a) Once approved it is the responsibility of the AP or a pharmacist acting on their behalf to contact the product sponsor/supplier to arrange importation/supply. The sponsor requires a copy of the TGA approval letter to release the stock.	☐
	(b) MDMA and psilocybine are included in Schedule 4 of the *Customs (Prohibited Imports) Regulations 1956*. Importers must ensure they obtain the necessary licence and/or permission from the Office of Drug Control (ODC) prior to importing the product. ODC can be contacted via email at ncs@health.gov.au.	☐
	(c) The psychiatrist/pharmacist must comply with state or territory laws around access/permits in relation to these substances. State/territory departments should be contacted directly for further information on these requirements.	☐
	(d) 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 within one month of that period ending). AP 6 monthly reports can be easily submitted using the SAS & Authorised Prescriber Online System.	☐