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

Renewal checklist for prescribing psychiatrists of MDMA and psilocybine

This checklist summarises key obligations for psychiatrists applying to **renew** an authorisation 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	Check
	(i) The psychiatrist must provide updated evidence of specific clinical experience and training applicable to the proposed use of the product. (ii) Details of supervisory arrangements and any proposed changes to these arrangements.	☐
2	**Product details and clinical evidence**	**Check**
	Evidence: Provide all available **new** 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).	☐
	Product: (i) Provide information on any changes in the product(s) to be used, including brand name, sponsor (supplier), dispensing pharmacy details and storage details. (ii) Provide details of any changes in logistics arrangements for supply of the product. (iii) Declare products continue to conform with GMP requirements, and the relevant Therapeutic Goods Order (see: Complying with the quality requirements for MDMA and psilocybine).	☐

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3	Protocol amendments	Check
	Please note that the clinical protocol must be submitted to the TGA for review with an application for renewal of an AP authorisation. Any amendments should be highlighted as tracked changes in the submitted document(s). **Any protocol amendments must be first approved by the HREC and submitted to the TGA for review. This includes, but is not limited to changes in any of the following:**	
	Practice location Include details of any location changes, additional site locations, or changes in the facilities available at the original site location.	☐
	Use and monitoring Any changes in the 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.	☐
	Efficacy and safety Changes to any known/expected adverse effects, risks including but not limited to how patient vulnerability will be managed, safety measures and related toxicology.	☐
	Participant selection Changes in process of screening for eligibility, inclusion and exclusion criteria and patient withdrawal process.	☐
	Consent process (please attach consent form and patient information 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.	☐
	Psychotherapy Changes in psychoeducation and preparation for the dose sessions, anxiety management strategies, strategies to monitor mental state and wellbeing, supporting staff management.	☐
	Supporting clinical therapists Any changes in the supporting therapists, including details of their qualifications and experience.	☐
4	**Obtain HREC approval**	**Check**
	Obtain an approval letter 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 is the responsibility of the HREC to decide whether their approval is provided as part of an extension application or if a new application is required.	☐
5	**Submit a new AP application**	**Check**
	(a) **HREC approval and clinical protocol** documentation are required for submission of the renewal AP application.	☐
	(b) Submit new application through the SAS & Authorised Prescriber Online System. Information on using the online portal system can be found in the Authorised Prescriber Scheme Online system guidance document.	☐

6	Other considerations
	(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. (e) **APs who have not submitted 6 monthly reports for previous approvals will not be considered for renewal.**