



SHPA submission to Targeted Consultation for Proposed Amendments to Drugs, Poisons and Controlled Substances Regulations 2017 - MDMA and psilocybine, May 2023

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA convenes a Mental Health Specialty Practice Group, comprising of a network of SHPA members who work in mental health units and any inpatient, outpatient, ambulatory or primary care settings where patients of any age with mental health conditions, receive pharmacy services. Members working in this area in particular would likely be participating in prescribing decisions, advice and monitoring for the use of MDMA and psilocybine.

SHPA's Victoria Branch Committee welcomes the opportunity to provide feedback to this consultation under each question below.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on yyik@shpa.org.au.

Consultation questions

1. Do you have any comments about the proposed approach to implementing the access controls in Appendix D of the amended Poisons Standard (i.e. restricting prescribing to specialist psychiatrists with Authorised Prescriber approval)?

SHPA supports the proposed approach to implement access controls for MDMA and psilocybine, which will restrict prescribing to psychiatrists with Authorised Prescriber approval or for use in TGA approved or notified clinical trials. This will ensure that while the evidence base and use in clinical practice grows, the medications have the appropriate oversight and monitoring required by specialists in the fields of Post Traumatic Stress Syndrome (PTSD) or treatment-resistant depression. This will not only maintain safe and appropriate access for consumers but also to prevent harms.

The specialist psychiatrist will also be able to determine the most appropriate clinical management required including monitoring post administration and the best suited setting for dosing.

SHPA anticipates that the specialist psychiatrist will submit adverse event reports to the TGA in order to maintain up to date data regarding consumer adverse events associated with MDMA and psilocybin.

2. Do you support the proposal to require Authorised Prescribers prescribing Schedule 8 MDMA and Schedule 8 psilocybine in Victoria to notify the Secretary to the Department of Health? If so, why? If not, why not?

As with other Schedule 8 medicines with the potential of misuse or diversion, SHPA believes it is appropriate to require Authorised Prescriber to notify the Secretary for the Department of Health when they administer, supply or prescribe Schedule 8 MDMA or psilocybine.

SHPA anticipates that the data collected will inform any required changes to regulatory settings for these medicines in future, as well as monitoring the supply chain and potential diversions.



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3. Do you anticipate Authorised Prescribers in Victoria might have any difficulties with complying with the proposed notification requirements?

SHPA does not anticipate difficulties for Authorised Prescribers complying with the proposed notification requirements given that they currently are required to do so for other scheduled medicines.

4. Do you support the proposal to limit the direct supply of Schedule 8 MDMA or Schedule 8 psilocybine to the administration to patients in a supervised clinical setting. If not, why?

SHPA understands that to reduce risks of diversion and harm, the administration of Schedule 8 MDMA and psilocybine would be most appropriate in clinical settings under supervision of a healthcare professional.

However, if this is to occur in inpatient or day hospital settings, consideration must be given to the required resources and staffing levels to facilitate this. Aside from supervision by the psychiatrist, administration will include nursing staff for monitoring pre- and post-administration of MDMA and psilocybine.

Given that administration will take place in hospital settings, this requirement will also necessitate access to specialist hospital mental health pharmacists to ensure appropriate medicines counselling takes place, as well as the provision of medicine information for other healthcare professionals. Given the emerging evidence base and lack of data concerning medicine interactions, contraindications, dosing and guidelines around the use of MDMA and psilocybine, access to mental health pharmacists or medicines information pharmacists will be required to support the provision of evidence based best practice and medicines information.

SHPA anticipates that the appropriate storage of Schedule 8 MDMA and psilocybine will occur in hospital dispensaries with associated schedule requirements. In addition, consideration must be given to the appropriate legal requirements for the administration, recording and dispensing of these scheduled medicines.

5. Do you have any comments of potential unintended consequences of the proposed amendments to the Regulations?

While SHPA supports consumer access to evidence-based medicines, novel psychoactive treatments may be proposed increasingly for scheduling changes following these amendments. Robust procedures and consultation will be required prior to approval of these treatments, with consideration to the additional resources and infrastructure required to support the prescribing, administration, dispensing and monitoring of these potential treatments.

Consideration must also be given to the training required to update healthcare professionals on the use of novel treatments such as contraindications, dosing and interactions. Mental health pharmacists and medicines information pharmacists are therefore a valuable resource in ensuring that this occurs in hospital settings.

