Proposed amendments – Drugs, Poisons and Controlled Substances Regulations 2017 (access controls for MDMA and psilocybine)

Stakeholder Consultation Paper April 2023

OFFICIAL

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Background information

The Commonwealth Poisons Standard

The Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard), provides a uniform approach to setting the availability and accessibility of certain controlled substances. The Australian Government Department of Health and Aged Care's Therapeutic Goods Administration (TGA) produces and updates this legislative instrument. States and Territories give effect to the Poisons Standard, through their relevant medicines and poisons legislation.

All states and territories have formally agreed to this approach under the *Australian Health Ministers' Advisory Council Scheduling Policy Framework for Medicines and Chemicals* (December 2017), which sets the national policy for applying access restrictions.

In Victoria, the Schedules of medicines and poisons (Schedule 2 to Schedule 9) in the Poisons Standard are given legal effect automatically by reference through the *Drugs, Poisons and Controlled Substances Act 1981* (the Act). Appendix D of the Poisons Standard is not given legal effect automatically but may

be adopted through amendments to the *Drugs Poisons and Controlled Substances Regulations 2017* (the Regulations), or instruments issued under the Act or Regulations (such as the Victorian Poisons Code).

TGA decision to amend the Poisons Standard

On 3 February 2023, the TGA published its final decision in response to an application to amend the Poisons Standard to down-schedule N,α-DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE (MDMA) and psilocybine, from Schedule 9 (prohibited substances) to Schedule 8 (controlled substances) in certain circumstances.

As a result of the decision, with effect from 1 July 2023 MDMA will be listed in Schedule 8 for the treatment of post-traumatic stress disorder (PTSD) and psilocybine will be listed in Schedule 8 for treatment-resistant depression (TRD). MDMA for the treatment of PTSD and psilocybine for treating TRD will also be in Schedule 8 if it is used in TGA approved or notified clinical trials. For all other uses, MDMA and psilocybine will remain in Schedule 9.

Under the TGA's decision, Appendix D of the Poisons Standard will also be amended, to restrict that only specialist psychiatrists who are authorised under the TGA's Authorised Prescriber Scheme will be able to prescribe Schedule 8 MDMA for PTSD and Schedule 8 psilocybine for TRD.

An excerpt from the final decision is found at Appendix 1 to this Consultation Paper.

Proposed amendments

In Victoria, the changes to schedules for MDMA and psilocybine in the Poisons Standard will be adopted automatically under the Act.[1] That is, from 1 July 2023, in Victoria the substances will be included in Schedule 8 as in the Poisons Standard.

The department is considering amendments to the Regulations to establish in Victoria the additional access controls provided in Appendix D of the amended Poisons Standard, and to establish further safeguards that are intended to protect patient safety, ensure national consistency, and minimise any risk of drug diversion.

The proposed amendments to the Regulations, and the rationale for their inclusion, are set out below.

Adopting the applicable restrictions in Appendix D of the amended Poisons Standard

The department proposes amendments to the Regulations, to provide that the prescribing, supply, or administration of Schedule 8 MDMA for PTSD and Schedule 8 psilocybine for TRD will be restricted to specialist psychiatrists who are approved under the TGA's Authorised Prescriber Scheme, or for use in TGA approved or notified clinical trials.

This will give legal effect to the specific restrictions in Appendix D in the amended Poisons Standard for these substances. These amendments will therefore align with the intention of the changes to the

[1] In the Act, the terms Schedule 8 poison and Schedule 9 poison are defined by reference to Schedules 8 and 9 in the Poisons Standard.

Poisons Standard, ensuring safe and appropriate patient access. The TGA considers specialist psychiatrists to have the training and expertise required to diagnose and appropriately treat PTSD with Schedule 8 MDMA or TRD with Schedule 8 psilocybine based on the emerging evidence for the use of these substances. The Authorised Prescriber scheme has safeguards in place including that the specialist psychiatrist:

- Must have approval by a Human Research Ethics Committee that is registered with the National Health and Medical Research Council.
- Treats according to a protocol that involves assessment and ongoing clinical management by the psychiatrist before and after administration of appropriately supervised single dosing of the patient in an appropriate setting (such as a day hospital or an inpatient setting).
- Is required to submit 6-monthly supply and adverse event reporting to the TGA.

More information about the TGA's Authorised Prescriber scheme can be found here.

Introducing a notification requirement

The Department proposes amendments to the Regulations, to introduce a requirement for the prescribing psychiatrist to notify the Secretary of the Department of Health when they consider it necessary to administer, supply, or prescribe Schedule 8 MDMA or Schedule 8 psilocybine.

A notification requirement would allow for timely State-based monitoring of Schedule 8 MDMA or Schedule 8 psilocybine. This will enable the Department to monitor and respond to any risk of diversion in the supply chain and ensure that the medications are only administered to those for whom they have been lawfully prescribed. The information collected through the notifications will also inform any shifts in risk assessment or proposed regulatory settings in the future.

It is anticipated that the details of the notification to be submitted will be set out in a form prescribed in the Regulations, and will include:

- Prescriber details
  - First name and surname
  - Practice address
  - Qualifications
  - TGA Authorisation number and Health Practitioner Regulation National Law registration number
  - Phone number
  - Email address
- Patient details
  - First name and surname
  - Address
  - Date of birth
  - Sex
- Name and address of site where the patient is receiving treatment
- Substance details
  - Name of substance
  - Proprietary name (if available)
  - Dose form and strength
  - Maximum dose and additional frequency
  - Anticipated date/s of administration
- Local Australian supplier details
  - Name and address of local Australian supplier (e.g. pharmacy or wholesaler)
- Details of other treatment (if applicable)
- Details of the clinical trial protocol (if applicable)

Prohibiting direct supply to patients

The department is considering amendments to the Regulations to prohibit the supply of Schedule 8 MDMA or Schedule 8 psilocybine to patients for unsupervised self-administration, to mitigate the risk of diversion and harm. The intention is to ensure that the medication is taken in a clinical setting under supervision.

This will align with the TGA's requirements for specialist psychiatrists under the Authorised Prescriber scheme that supply can only occur to patients 'under their immediate care,' and the TGA's published expectation that treatment will follow protocols established from current clinical trials and involve "assessment and on-going psycho-therapeutic management by the psychiatrist before and after administration of appropriately supervised single dosing of the patient in an appropriate setting (such as a day hospital or an inpatient setting)."

The evidence for use of these substances in clinical settings is emerging and may evolve rapidly. Further, the treatment protocols and various safeguards in the Authorised Prescriber process are being developed in parallel with State-based regulations. In that context, this requirement would ensure that the substances remain in clinical settings, and patients remain supervised while being treated with the substances, at this time, in accordance with the available clinical trials and evidence.

When the proposed amendments would come into effect

The department is working towards having the proposed amendments in place prior to 1 July 2023, to align with the date of the scheduling change and ensure appropriate protections are in place. This is subject to the conclusion of stakeholder consultation and processes for amendments to the Regulations.

Consultation questions

The following questions seek to capture stakeholder views on the proposed amendments to the Regulations. Stakeholders are invited to provide written comment in response to these questions and any other matters relevant to the proposals set out above.

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)?
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?
3. Do you anticipate Authorised Prescribers in Victoria might have any difficulties with complying with the proposed notification requirements?
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?
5. Do you have any comments of potential unintended consequences of the proposed amendments to the Regulations?

Due date for comments

Please provide comments in writing to Legislative and Regulatory Reform, Department of Health at legandregreform@health.vic.gov.au by **12 May 2023.**

To receive this document in another format, phone 1300 650 172, using the National Relay Service 13 36 77 if required, or email the Legislative and Regulatory Reform branch.

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

Appendix 1

Excerpt from Notice of final decisions to amend (or not amend) the current Poisons Standard in relation to psilocybine and MDMA (tga.gov.au)

The final decision in relation to psilocybine is as follows:

Schedule 9 – Amend entries

PSILOCYBINE except when included in Schedule 8.

Schedule 8 – New entries

PSILOCYBINE in preparations for human therapeutic use for the treatment of treatment-resistant depression.

Appendix D – New entries

5. Poisons for which possession without authority is illegal (e.g. possession other than in accordance with a legal prescription):

26A PSILOCYBINE.

10. Poison available only when prescribed or authorised in certain circumstances

PSILOCYBINE in preparations for human use may be supplied only for the treatment of treatment-resistant depression:

(a) if psilocybine is prescribed, or its supply is authorised, by a medical practitioner:

(i) registered under State or Territory legislation that forms part of the Health Practitioner Regulation National Law as a specialist psychiatrist; and

(ii) for whom an authority under subsection 19(5) of the Act that covers psilocybine is in force; or

(b) for use in a clinical trial that is approved by, or notified to, the Secretary under the Act.

The final decision in relation to MDMA is as follows:

Schedule 9 – Amend entries

N,α-DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA) except when included in Schedule 8.

Schedule 8 – New entries

N,α-DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA) in preparations for human therapeutic use for the treatment of post-traumatic stress disorder.

Appendix D – New entries

5. Poisons for which possession without authority is illegal (e.g. possession other than in accordance with a legal prescription): 22A N,α-DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA)

10. Poison available only when prescribed or authorised in certain circumstances N,α-DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA) in preparations for human use may be supplied only for the treatment of posttraumatic stress disorder:

(a) if MDMA is prescribed, or its supply is authorised, by a medical practitioner:

(i) registered under State or Territory legislation that forms part of the Health Practitioner Regulation National Law as a specialist psychiatrist; and

(ii) for whom an authority under subsection 19(5) of the Act that covers MDMA is in force; or

(b) for use in a clinical trial that is approved by, or notified to, the Secretary under the Act.