Consultation Document

Proposal to restrict permits for Schedule 9 poisons for human therapeutic use under the *Drugs, Poisons and Controlled Substances Regulations 2017* to clinical trials approved by a human research ethics committee.

OFFICIAL

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VICTORIA State Government | Department of Health

Contents

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Summary

This consultation document seeks feedback on the proposed *Drugs, Poisons and Controlled Substances Amendment (Schedule 9 Poisons) Regulations 2022*. The purpose of the proposed regulations is to ensure that access to Schedule 9 poisons in Victoria is in accordance with the national Scheduling Policy Framework for Medicines and Chemicals[1] (Scheduling Policy).

The proposed amendment limits the circumstances in which the Secretary to the Victorian Department of Health (the Secretary) may issue a Schedule 9 permit under section 33B of the *Drugs, Poisons and Controlled Substances Act 1981.* All administration, supply or prescribing of a Schedule 9 poison for human therapeutic use would be restricted to medical research, specifically a clinical trial approved by a human research ethics committee.

Consistent with this change, the proposed amendment prohibits the Secretary from issuing a 'general' Schedule 9 permit to a dentist under regulation 14 of the *Drugs, Poisons and Controlled Substances Regulation 2017* unless the administration, supply or prescription is to occur for the purposes of medical research.

The requirement for a medical practitioner or pharmacist to be issued a 'general' Schedule 9 permit is removed to avoid duplication and acknowledges that other controls exist to restrict the possession and use of Schedule 9 poisons.

Background

Schedule 9 Poisons

Schedule 9 poisons are regulated in Victoria under the *Drugs, Poisons and Controlled Substances Act 1981* (the Act). Schedule 9 poisons are those poisons listed in Schedule 9 of the Poisons Standard [2], and are adopted by reference in the Act.

The Poisons Standard classifies Schedule 9 poisons as a 'Prohibited Substances' and describes them as '*Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.*'

The Poisons Standard (June 2022) lists 159 poisons in Schedule 9. The schedule includes a number of poisons well known for illicit use with high potential for abuse, misuse and addiction. Examples of Schedule 9 poisons include:

- cannabis (except when separately specified in the schedules),
- clonazolam
- desomorphine
- 2,5-dimethoxyamfetamine (DMA)
- N, α -dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA)

[1] https://www.tga.gov.au/sites/default/files/ahmac-scheduling-policy-framework-medicines-and-chemicals.pdf

[2] https://www.tga.gov.au/publication/poisons-standard-susmp

- etorphine
- heroin
- 4-hydroxybutanoic acid and its salts except for sodium oxybate when in Schedule 8. (gamma hydroxybutyrate (GHB))
- lysergic acid
- methcathinone
- 3-methylfentanyl
- N,N-dimethyltryptamine (DMT)
- psilocybine
- phencyclidine (PCP).
- thiofentanyl

Currently, there is minimal human therapeutic use of Schedule 9 poisons in Australia. There are a small number of clinical trials involving Australian sites listed on clinical trial registries[3] that include the use of N, α -dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) and psilocybine.

Scheduling policy relevant to Schedule 9 poisons

Scheduling is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control required to protect public health and safety. The process for rescheduling is described in the Scheduling Handbook.[4]

The national Scheduling Policy endorsed by Australian Health Ministers' Advisory Council in December 2017 sets out the national policy for applying access restrictions and allows decision-makers, expert Advisory Committee(s), evaluators and the delegate of the Australian Government Department of Health to judge the best fit for new substances and to facilitate the rescheduling assessment process when an application for rescheduling is received or new knowledge or practice emerges.

The factors described in the Scheduling Policy when considering whether to include a poison in Schedule 9 of the Commonwealth Poisons Standard are:

1. *The substance is included in either Schedule IV to the United Nations Single Convention on Narcotic Drugs, 1961 or in Schedule I to the United Nations Convention on Psychotropic Substances 1971.*
2. *The substance has no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use.*

   A high level of control is required through prohibition of manufacture, possession, sale or use to prevent abuse, misuse or diversion into illicit activities.

These factors are a critical piece of scheduling policy and are intended to ensure national consistency in the application of public health risk considerations when making a scheduling decision.

[3] https://www.australianclinicaltrials.gov.au/clinical-trial-registries

[4] https://www.tga.gov.au/sites/default/files/scheduling-handbook-guidance-amending-poisons-standard.pdf

Proposed Amendments

The proposed amendments introduce two new definitions into the regulations:

> ***clinical trial*** *- a human clinical trial approved by a human research ethics committee*
>
> ***human research ethics committee*** *- a committee —*
>
> > *(a) registered with the National Health and Medical Research Council established under the* ***National Health and Medical Research Council Act 1992 (Cth)****; and*
> >
> > *(b) operating in accordance with the human research guidelines issued under the* ***National Health and Medical Research Council Act 1992 (Cth)***

These new definitions are used to restrict the circumstances for human therapeutic use of Schedule 9 poisons in Victoria. The Secretary to the Department of Health would be prohibited from issuing a Schedule 9 permit under section 33B of the Act authorising a medical practitioner to administer, supply or prescribe a Schedule 9 poison to a person unless the administration, supply or prescription is to occur for the purposes of the clinical trial specified in the Schedule 9 permit.

The amendments would require the Secretary to impose a condition under section 33B(2)(b) of the Act that limits the administration, supply or prescription of the Schedule 9 poison to the clinical trial specified in the permit.

The information to be included in the application form completed by a medical practitioner for a Schedule 9 permit is stated in Form 2 in Schedule 2 of the Regulations. The proposed amendment includes a revised form to clarify the information that a medical practitioner must provide when applying for a Schedule 9 permit. A draft of the amended form is included in Appendix 2.

The proposed regulations remove the requirement for a medical practitioner or pharmacist to apply for a general Schedule 9 permit. A general Schedule 9 permit is defined in the Regulations as a permit issued under regulation 14(1). This removes duplication requiring a medical practitioner to be issued a ‘patient specific’ permit under section 33B of the Act and a ‘general’ Schedule 9 permit under regulation 14(1). In effect, this means that a general Schedule 9 permit for human therapeutic use would only apply to dentists, where no mechanism for a dentist to apply for a permit under the Act currently exists. Whilst the Victorian Department of Health has never received an application for a general Schedule 9 permit from a dentist, it is acknowledged that there may be a circumstance in the future where a clinical trial involves a Schedule 9 poison for dental use.

The proposed regulations clarify that the Secretary to the Department of Health must not issue a general Schedule 9 permit authorising a dentist to administer, supply or prescribe a Schedule 9 poison to a person unless the administration, supply or prescription is to occur for the purposes of the clinical trial specified in the Schedule 9 permit.

It is proposed that a general Schedule 9 permit issued to a dentist is restricted to a specific patient.

The proposed amendment removes the requirement for a pharmacist to apply for and hold a general Schedule 9 permit. This proposal recognises that the requirement is unnecessary as pharmacists are not able to initiate supply or administer any Schedule 9 poisons without a medical practitioner’s or dentist’s instruction. Whether or not a pharmacist holds a general Schedule 9 permit does not change the fact that they cannot supply or administer a Schedule 9 poisons without directions from a medical practitioner or a dentist.

Currently, a general Schedule 9 permit may also authorise a pharmacist to manufacture, purchase, possess or use a specified Schedule 9 poison. However, the manufacture, purchase, possession and use of a Schedule 9 poisons by a pharmacist in the lawful practice of their profession is already

regulated elsewhere in the Act and Regulations. This additional requirement to hold a general Schedule 9 permit for pharmacists to manufacture, purchase, possess and use in their duties as a pharmacist is redundant.

The proposed regulations include consequential changes that reflect the fact that a general Schedule 9 permit is no longer applicable to medical practitioners or pharmacists.

Anticipated Impact by Stakeholder Group

Patients

The proposed amendments improve patient safety by ensuring all human therapeutic use of Schedule 9 poisons is restricted to clinical trials approved by a human research ethics committee and in accordance with the National Statement on Ethical Conduct in Human Research[5].

If a poison in Schedule 9 were found to have a legitimate human therapeutic use for the treatment of a patient it would fulfil the factors for Schedule 8 poisons described in the Scheduling Policy. A rescheduling application to amend the Poisons Standard may be made to the Secretary of the Australian Government Department of Health under section 52EAA of the *Therapeutic Goods Act 1989*. A change to scheduling would be automatically adopted in Victoria.

Medical Practitioners

The proposed amendments clarify the process a medical practitioner must follow when seeking to obtain, possess, supply, prescribe and/or use a Schedule 9 poison for human therapeutic use. The amendments include revisions to the prescribed form that specify the information and documents to be provided when a medical practitioner applies for a Schedule 9 permit under section 33B of the Act.

Dentists

The proposed amendments do not change the existing provision that a dentist may apply for general Schedule 9 permit to treat a patient with a Schedule 9 poison. The amendments clarify the requirement for a patient to be participating in a clinical trial and that a general Schedule 9 permit applies to a specific patient.

Veterinary Practitioners

Veterinary practitioners cannot obtain, possess, supply, prescribe or use a Schedule 9 poison for human therapeutic use. There are no changes proposed to the existing requirements for veterinary practitioners to obtain a general Schedule 9 permit for animal use.

[5] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Pharmacists

The proposed amendments recognise that a pharmacist can obtain, possess or supply a Schedule 9 poison in the lawful practice of their profession. The requirement for a pharmacist to be issued a general Schedule 9 permit is removed.

The proposed regulations will allow a pharmacist to supply or administer a Schedule 9 poison on the basis of an instruction of a medical practitioner or dentist.

A medical practitioner can only instruct a pharmacist to supply or administer Schedule 9 poisons if the medical practitioner has obtained a Schedule 9 permit under section 33B of the Act.

A dentist can only instruct a pharmacist to supply or administer Schedule 9 poisons if the dentist has obtained a general Schedule 9 permit under the Regulations.

This proposal to remove general Schedule 9 permit requirements for pharmacists recognises that this requirement is unnecessary as pharmacists are not able to initiate supply or administer any Schedule 9 poisons without a medical practitioner's or dentist's instruction. Whether the pharmacist holds a general Schedule 9 permit or not does not change the fact that they cannot supply or administer a Schedule 9 poisons without instructions from a medical practitioner or a dentist.

Other Jurisdictions

All States and Territories impose controls on the human therapeutic use of Schedule 9 poisons. New South Wales, the Northern Territory, Tasmania and Western Australia regulatory regimes expressly limit the human therapeutic use of Schedule 9 poisons to medical research. As far as the Victoria Department of Health is aware, no permit has been granted in any jurisdiction in Australia for the human therapeutic use of a Schedule 9 poison outside the controlled clinical trial environment.

Consultation Questions

The Victorian Department of Health is seeking responses from stakeholders to the following questions:

1. Do you support the proposed amendment that ensures Victoria follows the national Scheduling Policy that limits human therapeutic use of Schedule 9 poisons to a controlled clinical trial?
2. Do you have any comments on the proposed amendments?
3. Do you have any comments on the proposed prescribed form for the purposes of a medical practitioner applying for a Schedule 9 permit under section 33A of the Act, included in Appendix 1?

Please send responses to dpcs@health.vic.gov.au by **COB 28 August 2022.**

For further information please contact dpcs@health.vic.gov.au

Appendix 1 – Proposed form for the purposes of a medical practitioner applying for a Schedule 9 permit under section 33A of the Act

FORM 2

Regulation 128

Drugs, Poisons and Controlled Substances Regulations 2017

CLINICAL TRIAL WITH SCHEDULE 9 POISONS BY A REGISTERED MEDICAL PRACTITIONER

(Application for permit to administer, supply or prescribe)

FOR CLINICAL TRIAL WITH SCHEDULE 9 POISONS

Section 1: (To be completed in all cases)

Full name of patient

Date of birth Sex

Private address of patient Postcode

Full name and qualifications of registered medical practitioner

Address of registered medical practitioner Postcode

Telephone and fax no. of registered medical practitioner

Name and address of site where patient is participating in the clinical trial

Section 2:

Schedule 9 poison(s) for which permit is requested:

NAME OF SCHEDULE 9 POISON(S)	PROPRIETARY NAME (if available)	FORM (e.g. powder, vial, tablet)	STRENGTH	EXPECTED MAXIMUM DAILY DOSE

Name and address of supplier

Is this product registered for therapeutic use? If Yes, in which country/ies?

Section 3: Details of clinical trial

Name and registration number of the clinical trial

Purpose of clinical trial

Name of principal investigator(s) of the clinical trial

Registry that the clinical trial is registered on

Date that clinical trial was registered on the registry

Has the clinical trial received approval from a human research ethics committee?

Ethics approval number

Date ethics approval was granted

Date ethics approval expires

Name and registration number of the human research ethics committee that granted the ethics approval

Site/s that clinical trial approval has been granted for in Victoria

Section 4: Attachments

Human research ethics committee approval letter and clinical trial protocol

Signed patient consent form to be a part of clinical trial

Signature of registered medical practitioner

Date