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| Schedule 8 treatment permits |
| Requirements in Victoria |
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# Introductory notes

The *Drugs Poisons and Controlled Substances Act 1981* (the Act) and the Drugs Poisons and Controlled Substances Regulations 2017 (the regulations) indicate who may possess Schedule 4 and 8 poisons; the extent to which possession is lawful; and the legislative requirements for use, storage and supply of Schedule 4 and 8 poisons. Current versions of the Act and the regulations, which should be considered in concert and not in isolation, can be accessed at [Victorian Law Today](http://www.legislation.vic.gov.au/) <http://www.legislation.vic.gov.au/>.

This is one of a series of documents prepared by Medicines and Poisons Regulation (MPR) to assist multiple or specific categories of health practitioners to understand the more common legislative requirements. Refer to the [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.Vic website for other ‘Documents to print or download’ and for a link to the Poisons Standard, which contains details of poisons schedules plus labelling and packaging requirements.

## Evolution of the permit system

The permit system was introduced towards the middle of the 20th century in an attempt to limit a person’s ability to obtain Schedule 8 poisons from multiple prescribers. Since then, more health practitioners have been authorised to prescribe Schedule 8 poisons and the extent of prescribing (and of prescription-shopping) has significantly and progressively increased.

Numerous variations and exceptions to the original permit system, over many decades, made the permit system much more complex whereas problems associated with prescription-shopping and excessive prescribing of Schedule 8 poisons and many Schedule 4 poisons continued to increase.

To address the one of the primary reasons for having a permit system, Victoria introduced a monitored poisons database (SafeScript) that enables medical practitioners, nurse practitioners and pharmacists to review recent dispensing records for individual patients in order to make a better informed decision, about whether it is safe to prescribe one or more Schedule 8 poisons and/or monitored Schedule 4 poisons before doing so.

# Use of SafeScript

Since 1 April 2020, medical practitioners and nurse practitioners have been required to take ‘all reasonable steps’ to check the SafeScript database before prescribing a Schedule 8 poison (or a monitored Schedule 4 poison) to a patient – unless a specific exception applies.

For an explanation of the term ‘all reasonable steps’; how it relates to SafeScript; and exceptions to the mandatory requirement; please refer to the document ‘*All reasonable steps and other key terms*’, which is available on the MPR website as a ‘Document to print or download’.

**More information about** [**SafeScript**](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript) <https://www.health.vic.gov.au/drugs-and-poisons/safescript> (including online educational and training options), can be found on the Health.Vic website.

**To register to use SafeScript,** go to the [SafeScript website](https://www.safescript.vic.gov.au/) <https://www.safescript.vic.gov.au>

# How to use this document

When considering prescribing a Schedule 8 poison, please follow the following instructions, in order:

* Review pages 2 and 3; to determine whether any general or specific exceptions to permit requirements are applicable.
* If not, proceed to the series of FIVE questions, commencing on page 4:
	+ Ask the questions in the sequence shown until you can answer **‘yes’** to a question.
	+ When you can answer ‘**yes’** to a question, you need not consider the subsequent questions because you will have your answer.

# General exceptions(prisons, gaols, residential aged care services, inpatients)

In circumstances where patients are confined or not personally managing their medicines, the risk of concurrent prescribing and prescription-shopping is significantly reduced. Accordingly, a permit is not required to prescribe Schedule 8 poisons for:

* prisoners being treated in a prison or police gaol
* patients receiving inpatient treatment in a hospital
* patients receiving treatment in a hospital emergency department or a day procedure centre
	+ **Note**: Each of the preceding exceptions **includes** a period not exceeding 7 days following the release or discharge of the person from the corresponding establishments.
* Residents being treated in a residential aged care service

# Drug-dependent persons (no other exceptions)

Other than where a general exception applies, a medical practitioner or nurse practitioner **must obtain a permit before treating a drug-dependent person with a Schedule 8 poison**.

None of the following exceptions is applicable to permit requirements that relate to prescribing a Schedule 8 poison for a drug-dependent person.

# Other exceptions (for patients who are not drug-dependent persons)

Now that it is mandatory for a medical practitioner or nurse practitioner to check a patient’s SafeScript profile, **on each occasion**, **before prescribing a Schedule 8 poison for that patient**, additional exceptions apply to certain specified circumstances and/or specified specialist practitioners.

## Palliative care

A practitioner is not required to obtain a Schedule 8 treatment permit when the patient is suffering an incurable, progressive, far-advanced disease or medical condition; **and** the prognosis is of limited life expectancy due to the disease or medical condition; **and** the administration, supply or prescribing of **a Schedule 8 poison** is intended to provide palliative treatment.

## Pain caused by cancer or complications arising from cancer

Where the diagnosis is made by a registered medical practitioner; a treatment permit is not required to prescribe an **opioid analgesic** to treat pain caused by cancer or complications arising from cancer.

## Opioid analgesics (when the combined daily dosage of listed opioids does not exceed 100mg MED)

A practitioner is not required to obtain a Schedule 8 permit to prescribe one (or more) of the following **opioid** analgesic formulations **provided** the **combined daily dose** of **opioids listed below does not exceed 100 milligrams in morphine equivalence**.

* Oxycodone **oral or suppository**
* Morphine **oral**
* Hydromorphone **oral**
* Tapentadol **oral**
* Buprenorphine **patch**
* Fentanyl **patch**

**Note**:

* Checking a patient’s profile on SafeScript should be considered an essential step to determine the full extent of a patient’s use of opioid analgesics.

## Medicinal cannabis

A practitioner is not required to obtain a permit to prescribe Schedule 8 cannabis or Schedule 8 tetrahydrocannabinol for human therapeutic use if the following circumstances apply:

* the practitioner has obtained Commonwealth approval through the Special Access Scheme or Authorised prescriber scheme to administer, supply or prescribe Schedule 8 cannabis or Schedule 8 tetrahydrocannabinol for human therapeutic use for the patient; or
* the practitioner is administering, supplying or prescribing Schedule 8 cannabis or Schedule 8 tetrahydrocannabinol for human therapeutic use that is included in the Australian Register of Therapeutic Goods.

## Methadone

Notwithstanding the exceptions referred to above, **most** practitioners are required to hold a Schedule 8 permit **before prescribing,** administering or supplying **methadone** for any person (even on one occasion) **unless**:

* the practitioner is treating the patient at an oncology clinic in a hospital where the patient is **not** an in-patient; **or**
* the practitioner is treating the patient at a pain clinic in a hospital at which the patient is **not** an in-patient; **or**
* the patient is under the care of a palliative care service

# Permit requirements for most practitioners

If none of the preceding exceptions is applicable, consider the following five questions:

* When you can answer ‘**yes’** to a question, you need not consider the subsequent questions because you will have your answer.

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| Questions | Responses |
| 1. Do you (or another practitioner at the same clinic) hold a **current permit** to treat the patient with Schedule 8 poisons?
 | Where a current permit is held by one practitioner at a multiple-practitioner clinic, other practitioners at the same clinic may prescribe the specified Schedule 8 poison/s **provided** the prescribing is in accordance with any limits or conditions specified on the permit.* It is preferable if the permit is issued to the patient’s principal treating practitioner.
 |
| 1. Is there reason to believe the patient is a drug-dependent person?
 | You must **obtain** a permit **before** prescribing any Schedule 8 poison for the patient. * Refer to page 2 for **general exceptions**.
 |
| 1. Do you wish to treat a patient with any of the following **special Schedule 8 poisons**?
	* + methadone
		+ methylphenidate
		+ dexamphetamine or lisdexamfetamine
		+ amphetamine or methylamphetamine
		+ nabiximols (Sativex®)
		+ sodium oxybate
 | You must **obtain** a Schedule 8 permit **before** prescribing any special Schedule 8 poisons.* Refer to page 5 for exceptions that apply only to **paediatricians** and **psychiatrists** treating patients with ADHD.
* Page 3 shows exceptions that apply to **methadone**.
 |
| 1. Do you intend to **initiate** treatment with a Schedule 8 poison, which is **not** a special Schedule 8 poison, where the period of treatment does not exceed 8 weeks?
	* + **Note**: This question does not relate to inherited, transient or occasional patients who request a Schedule 8 poison.
 | You may **initiate** treatment without a permit - **provided** you do not prescribe or contribute to treatment for a **continuous period greater than 8 weeks**. * See below for an explanation of what is meant by ‘continuous period greater than 8 weeks’; and
* to review requirements for inherited, transient or occasional patients.
 |
| 1. Does your prescribing represent or contribute to treatment for a continuous period greater than 8 weeks (including prescribing by other prescribers)?
 | You must **obtain** or (at least) **apply** for a permit - even if you do not intend to prescribe on more than one occasion. * See pages 4 and 5 for more about this requirement.
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# Meaning of ‘continuous period greater than 8 weeks’

The legislation refers to treatment for a ‘continuous period greater than 8 weeks’ in relation to various permit requirements and exceptions but the term does **not** relate to the dates of consultations or prescriptions; it relates to the quantity of the drug that is prescribed or supplied. For example:

* A prescription for 100 tablets with directions of ‘one tablet twice daily’ corresponds to 50 days’ treatment (i.e. less than 8 weeks) whereas the same prescription with repeats authorised would correspond to providing treatment for a continuous period greater than 8 weeks.

# Inherited, transient and occasional patients

A practitioner who is not initiating treatment but considers it necessary to treat a patient with a Schedule 8 poison (other than where a permit must be obtained before prescribing) must **immediately apply for a permit** if there is reason to believe that issuing a prescription will contribute to a patient being treated for a **continuous period greater than 8 weeks - including the preceding period of treatment** (by any and all other prescriber/s).

* The mandatory requirement to check SafeScript is an essential step to enable a practitioner to fully assess the extent of previous prescribing and/or to determine whether the exception relating to opioid analgesics might apply (Refer to page 3 in relation to a total daily dosage of less than 100mg MED).
	+ The National Prescribing Service recommends that daily doses should not exceed 100mg in morphine equivalence (approximately 60 mg of oxycodone) without specialist advice.

To avoid delaying treatment for a genuine patient, a practitioner is authorised to treat the patient until the outcome of the permit application has been determined **provided** a permit application is submitted immediately – **even if there is no intention to treat or prescribe for the patient on subsequent occasions.**

This provision is intended to prevent drug-seeking patients (with or without genuine documentation) from obtaining multiple prescriptions from a clinic on the pretext that their regular treating practitioner is interstate, overseas or otherwise unavailable.

# Applying for a permit

Practitioners can apply for permits in SafeScript. Permit application forms are also located on the MPR website (<http://www.health.vic.gov.au/dpcs>).

# Paediatricians and psychiatrists(ONLY)

## **Attention deficit hyperactivity disorder** (patient less than 18 years old)

A **paediatrician** or a **psychiatrist** is not required to obtain a Schedule 8 treatment permit to treat a patient with a psychostimulant drug (approved by the TGA for the treatment of attention deficit hyperactivity disorder), **provided**:

* the patient is **not** a drug-dependent person; **and**
* the patient has not reached 18 years of age;

## **Attention deficit hyperactivity disorder** (patient is 18 years or more)

A **psychiatrist** is not required to obtain a Schedule 8 treatment permit to treat a patient with a psychostimulant drug (approved by the TGA for the treatment of attention deficit hyperactivity disorder), **provided** the patient is **not** a drug-dependent person;

# Opioid-replacement therapy (ORT)

Most medical practitioners wishing to prescribe methadone, buprenorphine (Subutex®), buprenorphine in combination with naloxone (Suboxone®) or long-acting injectable buprenorphine (Buvidal® and Sublocade®) to treat opioid-dependent patients, are required to undertake relevant training and assessment to gain approval from the department as ORT prescribers.

However, in recognition of the greater safety associated with the use of **Suboxone®** **film**, **Buvidal® and Sublocade®** any medical practitioner may now prescribe **Suboxone®** for up to 10 patients without undergoing the training or assessment to become an approved ORT prescriber.

* **Note**: The requirement to obtain a permit before prescribing a Schedule 8 poison for a drug-dependent person is still applicable.

Medical practitioners who are not approved ORT prescribers are advised to seek advice from an approved prescriber (preferably in the same practice or through the Drug and Alcohol Clinical Advisory Service (DACAS) before prescribing to a patient. Brief guides, in document and video format, are available on the MPR website in the section relating to ‘*Pharmacotherapy’*.

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

50 Lonsdale Street

Melbourne, 3000

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

Web: www.health.vic.gov.au/dpcs

* For information and details, relating to current, recent and pending Schedule 8 permits, please refer to the patient’s profile on the SafeScript database.
* For queries relating to the Act or regulations, please:
	+ refer to the ‘Documents to print or download’ that are available on the MPR website (see below); or
	+ if you are unable to address your query by referring to those documents, forward your query via e-mail to dpcs@health.vic.gov.au

## Documents to print or download from the MPR website

The [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.Vic website in the section for ‘Documents to print or download’, contains summaries of legislative requirements that have been prepared in relation to issues that relate to multiple categories of health practitioner as well as to individual categories of health practitioner. These documents, which are intended to assist health practitioners to comply with key legislative requirements, include the following:

* Issues relating to multiple categories of health practitioner, including:
	+ Possession and storage
	+ Supply, administration and recording
	+ Prescribing
	+ Criteria for lawful prescriptions
	+ All reasonable steps and other key terms
	+ Schedule 2 and 3 poisons
* Summaries that are specific to individual categories of health practitioner:
	+ Medical practitioners
	+ Pharmacists
	+ Nurses and midwives
	+ Nurses and midwives with registration endorsement (e.g. nurse practitioners, authorised midwives, etc.)
	+ Dentists (and other dental practitioners)
	+ Optometrists (and orthoptists)
	+ Podiatrists
	+ Veterinary practitioners

## Other possible sources of information

### Australian Health Practitioner Regulation Agency (Ahpra)

Web: [www.ahpra.gov.au](http://www.ahpra.gov.au)

### Drug and Alcohol Clinical Advisory Service (1800 812 804)

Registered health practitioners (only) may phone the **DACAS** at any time to seek **clinical advice** from specialists or other practitioners, who have been specially trained to provide advice in relation to pain, addiction and mental health issues, and for assistance with developing safe treatment plans, gradual dose tapering and alternative treatment options.

### Direct Line (1800 888 236)

* 24-hour confidential **drug and alcohol counselling** serviceforpatients
* 24-hour advisory service about available **treatment facilities** for patients, family or health practitioners

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