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| Medical practitioners |
| Key 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.

# Clarifying the meaning of key terms

The following explanations are provided in relation to terms that are in common use or contained within the Act and regulations.

* ‘**Administer**’ means to personally introduce a medicine to a person’s body or, in some cases, to personally supervise its introduction.
* ‘**Supply**’ means to provide a medicine that is to be used or administered at a later time.
* ‘**Dispense**’ is a commonly used term that is **not interchangeable** with ‘supply’. For example, a pharmacist might dispense a prescription with the intention of supplying the medicine but the supply might not occur until a later time (if at all). To avoid misunderstandings, the terms ‘administer’ and ‘supply’ are used in the legislation.
* ‘**Prescribe**’ is a term that commonly relates to the action of a practitioner who authorises treatment that may be carried out by another person. The 2017 Regulations describe this action in accordance with the three different mechanisms by which the treatment may be authorised; namely **‘issuing a prescription**’, ‘**writing a chart instruction**’ and ‘**authorising administration**’.
* In Victoria, the term ‘**drug of dependence**’ is used to describe substances, listed in Schedule 11 of the Act, which are known to be subject to misuse and trafficking. Note: The term is not limited to Schedule 8 and 9 poisons as some Schedule 4 poisons (e.g. benzodiazepines, pseudoephedrine, testosterone and other anabolic steroids) are also classified as drugs of dependence. However, most regulations relate primarily to whether a drug is a Schedule 4 or Schedule 8 poison (rather than a drug of dependence).
* The term ‘**as soon as practicable**’, where it appears in the legislation, is not to be interpreted as ‘when it is convenient’; for example, a person who is required to forward a document ‘as soon as practicable’ is required to do so not later than would be achieved by forwarding the required document via Australia Post.

# NOT the Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Scheme (PBS) is managed by Medicare Australia to **subsidise the cost** of listed medicines, including Authority Prescriptions for increased quantities of PBS listed medicines.

* Whether (or not) a medicine is prescribed under the PBS, on a PBS Authority Prescription, subsidised by another agency (e.g. WorkCover) or prescribed on a ‘private’ prescription has no bearing on whether it is lawful to prescribe or supply the medicine.
	+ Failure to comply with the Victorian Act and regulations renders a person liable to prosecution.

# Authorisation of medical practitioners

Medical practitioners are authorised to obtain, possess, use, supply or prescribe most medicines and poisons for the lawful practice of their profession (section 13 of the Act), i.e. for the medical treatment of patients under their care.

Accordingly, it is **not lawful** to prescribe:

* anabolic steroids for bodybuilding purposes or to enhance sporting performance
* stimulants to enhance or prolong wakefulness in long distance drivers, students, etc.
* drugs of dependence merely to support the drug-dependence of a person
* for persons who are not under the medical practitioner’s care, e.g. a person who has not consulted the medical practitioner and whose therapeutic need and/or identity cannot be confirmed

# Self-administration

Self-administration of a Schedule 4 or Schedule 8 poison is **prohibited** unless the medicine has been lawfully prescribed **and** supplied by another registered health practitioner (e.g. medical practitioner) or supplied by a pharmacist on a prescription from another registered health practitioner (regulation 105).

**Note**: This does **not** mean that once a medicine has been prescribed by a registered health practitioner, a medical practitioner may continue the treatment with medicines obtained from a wholesale supplier or by prescribing for self-administration.

# Prescribing and issuing prescriptions

A prescription is a document that authorises a pharmacist to supply prescribed medicines.

Medical practitioners who issue prescriptions are personally responsible for ensuring that the prescribed medicine is safe, appropriate and lawful. They should, therefore, ensure they are aware of the active ingredient/s and effects of prescribed medicines (especially as multiple brand names exist for many drugs) and should be wary when issuing a prescription for an unfamiliar medicine.

Before prescribing a Schedule 4 or Schedule 8 poison, a medical practitioner **must** take **all reasonable steps** toensure a therapeutic need exists **and**, before prescribing a drug of dependence, a medical practitioner **must** take all reasonable steps to confirm the identity of the patient.

Prescribing a Schedule 4 or Schedule 8 poison **merely** because a person requests a prescription will not satisfy these requirements.

## Taking ‘all reasonable steps’

To understand the meaning and application of the term ‘**all reasonable steps**’, medical practitioners are **strongly advised** to read the document, ‘*All reasonable steps and other key terms*’, which is available on the MPR website as a ‘Document to print or download’.

* Prescribing **merely** because another prescriber has done so is unlikely to satisfy these requirements.
* Whereas a medical practitioner might be considered to have taken all reasonable steps before prescribing a small quantity of a drug of dependence; the same steps might not be considered to be sufficient to prescribe (or supply) a larger quantity of the drug and/or to authorise repeat supplies.
	+ Medical practitioners are **not obliged** to prescribe the maximum PBS quantity of a medicine or any repeats – especially when a minimal quantity can address an immediate need whilst minimising the potential risks associated with drug-seeking behaviour.

## Criteria for lawful prescriptions

To ensure that their prescriptions are lawful, medical practitioners are **strongly advised** to read the document, ‘*Criteria for lawful prescriptions’*, which deals with handwritten, electronic and computer-generated prescriptions. It is available on the MPR website as a ‘Document to print or download’.

# SafeScript

**Since** 1 April 2020, medical practitioners, nurse practitioners and pharmacists have been required to take ‘all reasonable steps’ to check a patient’s SafeScript profile before issuing a prescription for (or supplying) any monitored supply poison to the patient.

## Monitored supply poisons

* all Schedule 8 medicines
* all benzodiazepines (e.g. diazepam; clonazepam)
* ‘Z-drugs’ (zolpidem, zopiclone)
* quetiapine
* gabapentin
* tramadol
* pregabalin
* codeine containing products

## Mandatory checking of the SafeScript database

The Act makes provision for penalties to be imposed when medical practitioners, nurse practitioners or pharmacists fail to take **‘all reasonable steps’** to check the SafeScript database before prescribing or supplying a monitored supply poison – **unless** otherwise specified in regulations 132F, 132G or 132H; (e.g. hospitals, prisons, police gaols, aged care and palliative care).

* While SafeScript has been designed to integrate with clinical workflows for clinicians using prescribing software, prescribers do not need to use their medical practice software to access the SafeScript database.
* Prescribers can access SafeScript directly (https://www.safescript.vic.gov.au/) via an internet browser.
* Prescribers who issue paper prescriptions can also access the SafeScript portal using mobile or tablet devices.

The phrase ‘all reasonable steps’ takes into consideration the possibility that, in addition to specified exceptions, there may be circumstances where practitioners may not be able to check the SafeScript database before prescribing or supplying a monitored supply poison. Accordingly, before considering whether action might be required in relation to non-compliance, the department will take account of the steps that were taken by a practitioner to attempt to satisfy this requirement plus any mitigating circumstances. For example, if access to the SafeScript database is temporarily unavailable:

* Contacting a pharmacy to enquire about a patient history in SafeScript
* Prescribing or supplying **limited quantities** and checking SafeScript at the next available opportunity

**However,** practitioners who do not check the SafeScript database simply because they have not registered to do so or have not arranged access to a computer (or other device), and do not take other measures to review a patient’s history in SafeScript, are unlikely to satisfy this requirement.

If practitioners are unable to check the SafeScript database, they would be expected to:

* make a prominent contemporaneous record of the fact and the reason they were unable to do so; to ensure that they (or colleagues) are aware, when the patient next attends, that the check was not done
* take all reasonable steps to ensure that they will be able to do so at the earliest opportunity; for example:
	+ If the practitioner has not registered to use SafeScript; to do so without delay.
	+ If a clinic does not have a suitable internet connection: ensure that another device (e.g. tablet or phone) can be used to connect to SafeScript / inform the proprietor/employer (in writing) of the need to arrange a suitable internet connection and forward a copy of that written advice to MPR.

**Note:** practitioners using software that is integrated with SafeScript will receive red, amber or green notifications when prescribing or supplying a monitored supply poison. These notifications are designed to quickly and clearly signal to the prescriber or pharmacist:

* The level of risk that may be associated with a patient being prescribed or supplied a monitored supply poison.
* The amount of time and effort likely to be required to examine the patient’s SafeScript profile to determine whether it is safe and appropriate to prescribe or supply.

The red, amber or green notifications **must not be relied upon** when making clinical decisions on whether it is safe and appropriate to prescribe or supply – the patient’s SafeScript profile **must** be checked **on each occasion** prior to prescribing or supplying a monitored supply poison unless a specific exception is applicable.

## Specified exceptions to mandatory checking of SafeScript

The following categories (in regulations 132F, 132G and 132H) are exceptions:

**A pharmacist** is not required to check SafeScript before supplying a monitored supply poison to:

* an in-patient being treated in hospital (**not** including discharge medicines);
* a patient being treated in an emergency department of a hospital (**not** including discharge medicines);
* a prisoner being treated in a prison;
* a person being treated in a police gaol;
* a resident being treated in an aged care service.

**Medical practitioners** and **nurse practitioners** are not required to check SafeScript before prescribing or supplying a monitored supply poison to:

* an in-patient being treated in, or discharged from, a hospital;
* a patient being treated in, or discharged from, an emergency department of a hospital;
* an out-patient being treated in, or discharged from, a hospital;
	+ **Note**: Whilst medical practitioners and nurse practitioners, working in hospitals (as per the three preceding dot points) are not legally required to check SafeScript; they are encouraged to do so to ensure that they are aware of information that might impact on the health and well-being of their patients.
* a prisoner being treated in a prison;
* a person being treated in a police gaol;
* a resident being treated in an aged care service.

### Incurable medical condition

**Medical practitioners, nurse practitioners** and **pharmacists** are not required to check SafeScript before prescribing or supplying a monitored supply poison to a person if:

* the person is suffering an incurable, progressive, far-advanced disease or medical condition; **and**
* the prognosis is of a limited life expectancy due to the disease or medical condition; **and**
* the supply of the monitored supply poison is intended to provide palliative treatment.

# Schedule 8 treatment permits

The legislation aims to minimise concurrent prescribing of Schedule 8 poisons by requiring prescribers to obtain Schedule 8 treatment permits and/or submit notifications in relation to specific patients – regardless of whether a Schedule 8 poison is prescribed under the Pharmaceutical Benefits Scheme.

Schedule 8 permit requirements used to be relatively simple with permits required to prescribe:

* Any Schedule 8 poison for a drug-dependent person – even on one occasion
* A Special Schedule 8 poison – even on one occasion
* Any other Schedule 8 poison for a continuous period greater than 8 weeks

However, requirements for Schedule 8 treatment permits are now subject to numerous exceptions and qualifications; so they have become very complex. Accordingly, medical practitioners are **strongly advised** to read the following documents on the MPR website to familiarise themselves with those requirements and **exceptions**:

* ‘Schedule 8 permit requirements’
* ‘Psychostimulants - Special Schedule 8 poisons for ADHD and narcolepsy’

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

# 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 these preparations 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’*.

# Schedule 4 poisons with special restrictions

**Retinoids** (e.g. acitretin, oral isotretinoin), **ovulatory stimulants** (clomiphene, cyclofenil), **prostaglandins** (e.g. dinoprost) plus **thalidomide** and **lenalidomide** are Schedule 4 poisons with which treatment for human patients may only be initiated by a medical practitioner who has the appropriate qualifications and expertise **and** who holds a **warrant** to prescribe the specific drug. These prescribers are required to endorse each prescription with their warrant number to demonstrate (to pharmacists) that they hold a warrant.

To address the possibility that patients might be unable to consult with an appropriate specialist practitioner, other practitioners may prescribe one of these drugs (without a warrant) when acting in accordance with the direction and approval of the warrant holder who usually treats the patient.

* In such cases, the prescription must be endorsed with the warrant holder’s name and warrant number to demonstrate (to pharmacists) that the prescribing has been authorised.

# 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)

### Medicare Australia (Pharmaceutical Benefits Scheme)

* Web: [www.medicareaustralia.gov.au/provider/](http://www.medicareaustralia.gov.au/provider/)
* General inquiries - 132 290
* Authorities - 1800 888 333

### 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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