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| Prescribing |
| Requirements for health practitioners |
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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, prescribing 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).

# All reasonable steps

The regulations state that health practitioners **must not** prescribe (or otherwise authorise treatment) unless they have taken ‘all reasonable steps’ (e.g. regulations 17(c) and 17(e) for medical practitioners; regulation 51 for pharmacists).

Whilst this is a subjective requirement, the regulation is written in such a way that it is the prescriber who must be able to demonstrate that all reasonable steps had been taken. Complying with this requirement is unlikely to be achieved if a health practitioner prescribes or supplies a scheduled medicine merely because a patient (or another health practitioner) requests that they do so.

Health practitioners are **strongly advised** to read the document ‘*All reasonable steps plus other key terms*’ to gain an understanding of how compliance might be achieved in different circumstances (e.g.; what steps were taken; what other steps might have been taken; what quantity was prescribed; what would another health practitioner have done in a similar situation.

# Prescribing and otherwise authorising treatment

Health practitioners, who are authorised to ‘issue a prescription’, ‘write a chart instruction’ or ‘authorise administration’ of a Schedule 4 or 8 poison, are commonly required to do so in writing, although the regulations do make provision for verbal instructions or transmission of digital images, if the practitioner is of the opinion that an **emergency** exists.

Computer-generated prescriptions and electronic prescriptions may also be lawful – provided such prescriptions comply with the criteria for such prescriptions, which have been approved by the Secretary.

## Emergency verbal instructions

A health practitioner, who is of the opinion that an **emergency** exists, may give an authorisation verbally (to a nurse, midwife or pharmacist) to **administer** a Schedule 4 or Schedule 8 poison - provided written confirmation of the verbal authorisation is provided, **as soon as practicable**, for inclusion in the treatment records of the person concerned.

Similarly, a health practitioner, who is of the opinion that an emergency exists, may give an authorisation verbally to a **pharmacist to supply** a Schedule 4 or Schedule 8 poison - provided written confirmation (usually in the form of a prescription) is sent to the pharmacist, **within 72 hours of issuing the verbal authorisation.**

The phrase ‘**as soon as practicable**’ is used to allow some flexibility according to the circumstances. The dictionary defines ‘practicable’ as ‘capable of being done’, ’feasible’. Accordingly, some circumstances will demand a rapid provision of the written instruction while a less speedy response may be acceptable in others. For example, where verbal instructions are given to a nurse to authorise administration of a medicine, confirmation in writing could be readily transmitted in the form of a facsimile or posted so that it can arrive with the next mail delivery.

## Emergency transmission of a digital image

A health practitioner, who is of the opinion that an **emergency** exists, may transmit a digital image of an original prescription to a **pharmacist to supply** a Schedule 4 or Schedule 8 poison – provided:

* The original prescription **complies** with regulatory requirements for handwritten and/or computer-generated prescriptions.
* The digital image of the original prescription is transmitted **directly to the pharmacist or pharmacy** of the patient’s choice by electronic means.
* The digital image of the original prescription is **not sent** to more than one pharmacy **or to a person other than a pharmacist.**
* The original prescription is sent to the pharmacist or pharmacy **within 72 hours of transmitting the digital image of the prescription.**

# Issuing prescriptions

An **original prescription** is a document that authorises a pharmacist to supply prescribed medicines; pharmacists are not authorised to supply on the basis of facsimiles or other scanned copies of prescriptions, except in emergency circumstances that are detailed above.

Health practitioners are not authorised to prescribe a Schedule 3, Schedule 4 or Schedule 8 poison **merely** because a person requests a prescription.

Before issuing a prescription, a prescriber must take **all reasonable steps** toensure a **therapeutic need** exists and, before issuing a prescription for a **drug of dependence**, a prescriber must take all reasonable steps to **confirm the identity** of the patient. Issuing a prescription, merely because another prescriber has done so, is unlikely to satisfy these requirements.

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.

## Required components of a prescription

Registered health practitioners are strongly advised to read another document in this series, ‘*Criteria for lawful prescriptions*’ for details of the regulatory requirements of handwritten, electronic and computer-generated prescriptions.

# Mandatory checking of the SafeScript database

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

Medical practitioners and nurse practitioners are **advised** to read the document ‘*All reasonable steps plus other key terms*’ to familiarise themselves with possible **exceptions** and of possible action to be taken if it is not possible to check SafeScript.

# Authorising administration

Registered health practitioners who authorise another health practitioner (e.g. nurse) to administer a Schedule 4 or Schedule 8 poison must:

* provide that authorisation **in writing** in a legible and durable form that names the person to whom the poison is to be administered; and
* date and confirm that authorisation with their **signature**

**Note**: These requirements do **not** exclude:

* written instructions that are not handwritten (e.g. computer-generated medication charts)
* signatures that are not handwritten (e.g. electronically transmitted orders)
* the transmission of instructions by facsimile

# Chart instructions

Where a registered health practitioner ‘writes a chart instruction’ by completing a ‘hospital medication chart’ or ‘residential medication chart’ in accordance with the definitions and requirements of those terms (as defined in the regulations), the chart instruction may serve as both an authorisation for administration and as an authorisation for a pharmacist to supply the specified medicines.

The provision, for pharmacists to supply medicines on the basis chart instructions (i.e. without an original prescription) was included in the regulations to authorise pharmacists to supply medicines in accordance with provisions of the Pharmaceutical Benefits Scheme (PBS).

* While this provision is not limited to medicines that attract a subsidy under the PBS or to practitioners who are approved to prescribe under the PBS; **the provision is limited to**:
  + the supply of Schedule 4 medicines on a **paper** residential medication chart;
  + the supply of Schedule 4 and Schedule 8 medicines on an **electronic** residential medications chart;
  + chart instructions on a residential medication chart or an electronic residential medication chart that complies with the Commonwealth regulations for the National Residential Medication Charts (NRMC or eNRMC).

# Permits for Schedule 8 poisons

The legislation aims to minimise concurrent prescribing of Schedule 8 poisons by requiring principal prescribers to obtain treatment permits in relation to specific patients.

Requirements for Schedule 8 permits can vary according to the circumstances of the patient or the qualifications of the health practitioner. Practitioners who are authorised to prescribe Schedule 8 poisons to treat human patients are strongly advised to familiarise themselves with requirements for Schedule 8 permits before prescribing a Schedule 8 poison.

Please refer to the MPR website and the document, ‘*Schedule 8 permit requirements’* for details of requirements and **exceptions**. Practitioners can apply for permits in SafeScript. Permit application forms are also located on the MPR website (<http://www.health.vic.gov.au/dpcs>).

# 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.

# Self-administration and self-prescribing

Self-administration of a Schedule 4 or Schedule 8 poison is **unlawful** 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 another registered health practitioner, a health practitioner may continue the treatment with medicine obtained from a wholesale supplier or by issuing a prescription and naming themselves as the patient.

# Supplying Schedule 4 and Schedule 8 poisons

Health practitioners who are authorised to supply Schedule 4 or Schedule 8 poisons are responsible for ensuring that each container of a medicine is labelled in accordance with the specifications for ‘dispensed medicines’ contained in the Poisons Standard (adopted under section 27A of the Act) plus the provisions of regulation 72 (where applicable). This responsibility **cannot** be delegated to another person. For specific details, please refer to the Poisons Standard (Part 2 section1.5.6 plus Appendices L and K); a link to the Poisons Standard is located in the ‘*Related sites*’ section of the MPR website.

## Labelling dispensed medicines

The required components of a label on medicines dispensed by health practitioners, which must not be less than 1.5 mm in size, include:

* the approved name of the poison or controlled substance or a proprietary name that unambiguously identifies the poison or controlled substance plus the strength, form (e.g. tablets) and quantity supplied
* the words “KEEP OUT OF REACH OF CHILDREN” in red on a white background
* if the medicine is intended for external use only, the word “POISON”, or the words “FOR EXTERNAL USE ONLY”, in red on a white background
* adequate directions for use **unless:**
  + the directions are complex and the practitioner has supplied separate written instructions, **or**
  + the medicine is to be administered by a registered health practitioner (e.g. nurse, medical practitioner)
  + the date on which supply is made or the dispensing is recorded (It is recognised that date on which supply is made may differ from the date on which a medicine is dispensed in anticipation of later supplying the medicine).
* the name, address and telephone number of the practitioner supplying the medicine
* the mandatory ‘sedation warning’ for a substance listed in Appendix K of the Poisons Standard
* the name of the **person** for whom the medicine was dispensed

**Note**: Additional information, about labelling requirements for **veterinary practitioners** and **pharmacists**, are contained in the corresponding document for each of those practitioners.

**Containers** must be impervious to the contents, sufficiently sturdy to prevent leakage and capable of being securely re-closed.

# Software

The Victorian Department of Health (DH) does **not** approve software for use by health practitioners; there is no legislative provision to do so. Accordingly, any claims by a software supplier, that the department has approved its software for use in Victoria, are not correct.

It is the responsibility of health practitioners to comply with the provisions of the Act and regulations and to ensure that any selected software enables them to do so. Therefore, it is advisable to seek confirmation, from prospective software suppliers, that software will enable the health practitioner to comply with the legislation **and** that following the provided operating instructions will ensure compliance with the legislation.

# Matters to be reported to MPR and/or police

For information about matters to be reported and how to submit reports, please refer to the document ‘Possession and storage of Schedule 4 and 8 poisons’.

# 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](http://www.health.vic.gov.au/dpcs)

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, please forward your query via e-mail to [dpcs@health.vic.gov.au](mailto: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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