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| Supply, administration and recording |
| (Schedule 4 and Schedule 8 poisons) |
| OFFICIAL |

# 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.

# Authorisation of health practitioners

It is unlawful to possess a Schedule 4 or Schedule 8 poisons unless specifically authorised by the Act or the regulations. Health practitioners are generally authorised **only** in the lawful practice of their professions and that authorisation is commonly limited or conditional. Refer to the document ‘Possession and storage of Schedule 4 and 8 poisons’ for further information.

However, when acting in another role, a health practitioner’s authorisation and responsibilities will be those that apply to the corresponding role (regulation 7). Common examples of other roles are shown below:

* A health practitioner for whom a medicine has been lawfully prescribed or supplied by another health practitioner (e.g. a prescription from a medical practitioner that is dispensed and supplied by a pharmacist) will have responsibilities consistent with those of any **patient** who has been supplied, lawfully, with that medicine.
* A nurse who assists a person in the administration of their own lawfully-supplied medicine will have responsibilities consistent with those of a **carer;** rather than those of a nurse.
* A health practitioner who transports a lawfully-supplied medicine to the patient for whom it is intended will have responsibilities consistent with those of a **courier**.

## 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.

# All reasonable steps

Where the regulations require health practitioners to take ‘all reasonable steps’ (e.g. regulations 17(c) and 17(e) for medical practitioners; regulation 51 for pharmacists); an objective test must be applied to the particular circumstances as to whether or not the steps taken were sufficient. Such a test would involve considering if the steps taken would be in accordance with those an ordinary competent person, or member of the corresponding profession, would take if put in that situation.

Complying with this requirement might not 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. Registered 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.

# 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.

# Recording transactions in Schedule 4 and 8 poisons

Regulation 108 requires health practitioners, as soon as practicable after completing a transaction, to:

* make true and accurate records of all Schedule 4 and Schedule 8 poisons **administered** or **supplied**
* retain those records for 3 years **and** produce them (on demand) to an authorised officer

Details to be contained in records of administration and supply include:

* the name and address (or location) of the person to whom the Schedule 4 poison or 8 poison is **supplied** or **administered**
* the date of the transaction
* the name, form, strength and quantity of the poison or controlled substance
* the name of the person carrying out the **administration** or **supply**
* in the case of a transaction involving supply on a prescription or medication chart instructions—
	+ the name of the person who wrote the prescription or chart instruction
	+ the directions for use as set out on the prescription or chart instruction
* in the case of a Schedule 8 poison purchased or obtained, the name and address of the person from whom the poison was purchased or obtained

Patient records (retained for at least 7 years to satisfy other legislative requirements) showing full details of drugs administered or supplied may be sufficient for Schedule 4 poisons but for Schedule 8 poisons a separate record is also required.

Records for Schedule 8 poisons must be in a form that shows the true and accurate balance remaining after each transaction and must be in a form that cannot be altered or deleted without detection. **Note**: A computer spreadsheet is unlikely to comply with this requirement; so manual records or suitable (specifically designed) computer software will likely be required.

A bound book, with consecutively-numbered pages, is a common option for health practitioners with limited transactions in Schedule 8 poisons. Loose-leaf pages do **not** satisfy the regulatory requirements. A drug register or administration book might be available from pharmaceutical wholesalers.

**Notes:**

* The regulations do not specify a mandatory frequency of stock checks but to ensure a true and accurate balance is recorded, it may be necessary to confirm the stock on hand at the completion of a transaction, rather than assuming that a calculated balance is accurate.
	+ Frequent stock checks are recommended, especially where more than one person has access to the Schedule 8 poisons.
* One Schedule 8 poisons register may be used to record transactions on behalf of multiple registered health practitioners using the same storage facility but, in some cases, to adequately account for all transactions (e.g. multiple medical practitioners at the same clinic) each practitioner might need to maintain a separate register to account for Schedule 8 poisons supplied to him or her.
	+ In either event, the Schedule 8 poison register (or registers) must account for all transactions including, for example, Schedule 8 poisons removed from and returned to the storage facility when the drug is transported for use in another place (e.g. doctors bag stock transported for house calls).

# 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.

# Passwords

Health practitioners who record transactions electronically must take **all reasonable steps** to ensure their personal access code for recording transactions in Schedule 8 poisons is not known or used by another person (regulation 109). In this case, ‘all reasonable steps’ would include selecting a password that could not be easily guessed by another person.

# Destruction of Schedule 8 poisons

Regulation 115 authorises dentists, medical practitioners, nurse practitioners, pharmacists, veterinary practitioners and authorised midwives to destroy a Schedule 8 poison in the presence of a witness who is a registered health practitioner (from one of the categories listed above) or a registered nurse or midwife.

**Note**: As nurses and midwives are not ‘authorised persons’ (under the Act), they may act only as witnesses and cannot take responsibility for destroying Schedule 8 poisons, other than in circumstances, relating to the contents or partially used ampoules, tablets and lozenges, which are specific exceptions in the regulations.

Details relating to the destruction of Schedule 8 poisons will generally be recorded within the Schedule 8 poison register or administration book/s in order to satisfy other regulatory requirements relating to records for Schedule 8 poisons.

Where Schedule 8 poisons are destroyed in greater quantities (e.g. hospital pharmacy department), a ‘Drugs for destruction register’ is commonly used with Schedule 8 poison entered into the register when they are entered out of another register.

# 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

GPO Box 4057

Melbourne 3001

Tel: 1300 364 545

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

Web: www2.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) and indicate, in the ‘Subject’ field, that your query is to be directed to:
	+ The Health Practitioner Compliance team – for matters relating to compliance by medical practitioners, veterinary practitioners, dentists and pharmacists.
	+ The Licence and Permit team – for matters relating to Health Services Permit holders (e.g. hospitals) and residential aged care services.

## 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)

#### Registration Boards (for treatment of human patients)

Refer to the Ahpra website for links to individual registration boards.

### Veterinary Practitioner Registration Board of Victoria

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

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