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| Dispensing medicines |
| (Requirements for pharmacists) |
| 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 medicines; the extent to which possession is lawful; and the legislative requirements for use, storage, and supply of Schedule 4 and 8 medicines. 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](https://www.health.vic.gov.au/drugs-and-poisons/documents-and-forms-to-print-or-download-medicines-and-poisons-regulation)’ 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**’.
* **’Drug of dependence**’ means a substance, 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).
* **‘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.
* **Emergency**’ means a sudden and urgent occasion for action.

# Chart instructions vs prescriptions

Whereas ‘**chart instructions**’ serve, primarily, to authorise administration by health practitioners (e.g. nurses); ‘**prescriptions**’ are documents that authorise pharmacists to supply prescribed medicines. The terms ‘prescription’ and ‘chart instruction’ are defined or explained in regulations 5 and 6.

The Commonwealth National Health (Pharmaceutical Benefits) Regulations 2017 make a distinction between a ‘**hospital medication chart**’ and a ‘**residential medication chart**’, which are used to authorise administration and **might** also serve to authorise pharmacists to supply medicines for the treatment of patients being treated in or at a hospital or day procedure centre and in residential aged care services, respectively.

Provision for pharmacists to supply medicines on the basis of **‘chart instructions’** was included in the regulations so that the provisions of the Commonwealth Regulations became lawful in Victoria - without limiting those provisions to medicines that are listed on the PBS or to prescribers who are authorised to prescribe PBS items.

**Note**: While ‘chart instructions’ **might** authorise a pharmacist to supply medicines; in most cases they do not fulfil the specifications of a prescription and pharmacists must comply with the regulations that are specific to supplying on the basis of a ‘chart instruction’ **or** a ‘prescription’, as the case may be.

* Pharmacists are advised to refer to the ‘Document to print or download’ relating to ‘*Supplying medicines to residential aged care*’ for further information and clarification.

# Electronic prescriptions

A person who issues an electronic prescription must comply with the Criteria for Electronic Prescriptions specified by the Secretary.

A pharmacist may only dispense an electronic prescription if it complies with the criteria specified by the Secretary, including the use of **software** that is listed on the Australian Digital Health Agency’s (ADHA) Electronic Prescribing Conformance Register with a current Conformance Identifier.

Pharmacists with questions relating to how the software they are using allows them to comply with their legislative responsibilities – e.g. the manner in which electronic prescriptions are retained and produced - should contact their software vendor.

# Additional required components of prescriptions

Regulation 24 lists the required components of a prescription, including the following (relatively recent) **additional** requirements.

* Where directions for the precise dose or frequency of administration cannot be included or a variable dosage regimen is directed (e.g. 1 to 2 tablets when necessary); the prescriber must include a statement specifying a maximum frequency of administration (e.g. not more than 4 tablets daily).

#### Prescriptions for Schedule 8 medicines and Schedule 4 monitored medicines

* The **date of birth** of the patient **must** be recorded on all prescriptions for Schedule 8 medicines **and** Schedule 4 monitored medicines.
* A statement in words (not just figures) indicating that the drug is to be supplied on only one occasion (e.g. NIL repeats) **must** be included on prescriptions for Schedule 8 medicines unless repeats are authorised.

# How to deal with non-compliant prescriptions

This section has been included to clarify a pharmacist’s responsibilities in the event that a prescription does not contain all components required by the regulations.

It is the responsibility of the prescriber to comply with the regulatory requirements for the components of a prescription. It is the responsibility of the pharmacist to accurately interpret the prescriber’s intentions and, in doing so, to ensure the prescribed medicine is safe and appropriate for administration by the patient.

A pharmacist who is presented with a prescription, which does not contain every required component, need not send the prescription back to the prescriber to have it amended. The steps that might be taken by a pharmacist are a matter of professional judgement; to be decided after considering relevant factors, e.g.

* If it is necessary to confirm or clarify a prescriber’s intentions, it is often sufficient to communicate with the prescriber in an unambiguous manner.
	+ In such cases, a contemporaneous note, in the form of a professional message in the dispensing records and/or an endorsement on the prescription (especially if repeat supplies are authorised), is strongly recommended.
* Sometimes the absence of a required component (e.g. a warrant number on a prescription for an ovulatory stimulant) could raise doubts about whether the medicine should have been prescribed by the noted prescriber and/or whether it is safe or appropriate to supply the prescribed medicine (see below).
* Where a required component is intended to prevent unlawful supply (e.g. the quantity of a Schedule 8 medicine not recorded in words as well as figures), it is likely that a pharmacist will need to communicate with the prescriber if there is any possibility that the prescribed quantity might have been amended.
* Sometimes an omission will be trivial and the pharmacist will not need to contact the prescriber at all.

**Note:** Handwritten components are not required on electronic prescriptions for S8 medicines and S4 drugs of dependence, which comply with the Criteria for Electronic Prescriptions approved by the Secretary.

#### Warrants for specified Schedule 4 medicines

Medical practitioners in Victoria **must** **endorse** prescriptions for ovulatory stimulants, prostaglandins, oral retinoids, thalidomide and lenalidomide with a **warrant number** (regulation 125), which is issued only to suitably qualified specialist practitioners.

Other medical practitioners must not prescribe these drugs without the expressed approval of a specialist who initiated or is continuing a patient’s treatment; in which case, the practitioner who issues it **must endorse** the prescription with the name **and** warrant number of that specialist.

Where prescriptions for these drugs have not been endorsed in the required manner, pharmacists should consider the possibility that the prescriber is unaware of the regulatory requirement and might not be acting in accordance with the advice of a specialist practitioner. Under such circumstances, a pharmacist would have reason to question whether the noted prescribing is safe, appropriate, or lawful.

# Varying from instructions on a prescription

To address concerns that pharmacists have been supplying medicine, on prescriptions, contrary to prescribers’ expressed intentions, regulations 50 and 51 make it an offence for a pharmacist to supply a Schedule 4 or Schedule 8 medicines contrary to the instructions written on a prescription - other than in accordance with exceptional circumstances, as indicated in regulation 53.

Examples of the instructions that are not to be varied include:

* Supplying a quantity that exceeds the quantity authorised for supply on the first (single) occasion, e.g. supplying multiple repeats when the prescriber has not endorsed the prescription to authorise doing so.
* Providing a repeat supply before an interval specified on a prescription (if any) has elapsed.
* Supplying a different brand of a medicine where the prescription specifies that **only** a specific brand of the medicine is to be supplied (i.e. when the prescriber has indicated that ‘brand substitution is not permitted’)

## Exceptional circumstances

A pharmacist who believes it is necessary to vary from a prescription’s stated instructions in exceptional circumstances is required to **first** take reasonable steps to obtain the prescriber’s consent but, if unable to contact the prescriber-

* Where the variation is **requested** by or on behalf of the person named on the prescription, the pharmacist:
	+ must be satisfied that not to vary from the prescription would impose an **unreasonable** difficulty or inconvenience on the patient; and
	+ must take all reasonable steps to ensure that supplying the Schedule 4 or Schedule 8 medicine, as requested, would not represent an unacceptable risk to the health and safety of the patient: and
	+ must not supply a quantity that exceeds the quantity requested (if any)
* Where, at the time that the prescription is presented, it is not reasonably practicable for the pharmacist to comply with the instructions written on the prescription:
	+ the pharmacist must take all reasonable steps to ensure that supplying the Schedule 4 or Schedule 8 medicine, as proposed, would not represent an unacceptable risk to the health and safety of the patient: and
	+ the patient must consent to the variation from the instructions

### Recording

Regulation 68 requires a pharmacist who varies from the instructions of a prescription, without the consent of the prescriber, to:

* inform the prescriber **as soon as practicable** after the supply; and
* make a record (i.e. in connection with the corresponding dispensing record) to confirm that the exceptional circumstances existed in relation to that supply

# Emergency directions from a prescriber

Medical practitioners and other suitably registered health practitioners may issue a verbal instruction or transmit a digital image of an original paper prescription to a pharmacist to supply a Schedule 4 or a Schedule 8 medicine if, in the opinion of the prescriber, an emergency exists (Regulation 25 and Regulation 25A). The prescriber who issues a verbal instruction **must** ensure that the written confirmation (most commonly in the form of a prescription) is sent to the pharmacist within 72 hours of issuing the verbal instruction. A prescriber who transmits a digital image of an original paper prescription **must** ensure that the original paper prescription is sent to the pharmacist within 72 hours of transmitting the digital image.

**Note**:

* The digital image of the original paper prescription must be transmitted directly to the pharmacist or pharmacy of the patient's choice by electronic means. Electronic means may include secure email, fax or Multimedia Messaging Service (MMS).
* The digital image of the original paper prescription must not be sent to more than one pharmacy or to a person other than a pharmacist.
* The prescriber is responsible for ensuring that the written confirmation is sent to the pharmacist, though may delegate the steps to complete the task to another person. The act of sending the original paper prescription must be completed within 72 hours. Due to potential for postage delays it is not a legal requirement that the original paper prescription is received by the pharmacist within 72 hours.
* An electronic prescription should be used in preference to transmission a digital image of an original paper prescription, where available and suitable for the patient.
* It is the responsibility of the prescriber to ensure that an ‘owed’ prescription is provided to the pharmacist.
	+ Relying on a patient to deliver an ‘owed’ prescription to the pharmacy can be unwise.
* If it is necessary to cancel a dispensing record and recreate it, in order to make a claim under the Pharmaceutical Benefits Scheme when an owed prescription (i.e. following a verbal order from the prescriber) is received, the new record must not be false or misleading. In such a situation, it is recommended that a prominent comment is recorded in the ‘dosage instructions’ field to clarify what occurred (e.g. “SCRIPT RECEIVED REGARDING SUPPLY ON DATE”).

# Labelling dispensed medicines

Pharmacists 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.

The required components of a label on medicines dispensed by pharmacists, 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 pharmacy supplying the medicine
* the mandatory ‘sedation warning’ for a substance listed in Appendix K of the Poisons Standard
* where supply is made on prescription, the prescription reference number
* the date on which supply is made or the dispensing is recorded (unless that date is clear from the prescription reference number)
	+ 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 of the **person** for whom the medicine was dispensed, **OR**
* if the medicine is for the treatment of an **animal**, the label must include—
	+ the species, age, breed, and sex of the animal; and
	+ the name of the person who owns or has custody or care of the animal

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

# Marking dispensed prescriptions

A pharmacist who supplies Schedule 4 or Schedule 8 medicines on a prescription must ensure that the prescription (or copy) is marked in a **durable** form in a way that indicates:

* that supply has occurred; and
* the name of the supplying pharmacy; and
* the date of supply or dispensing (regulation 60).

Compliance with this requirement might be achieved by using:

* an adhesive sticker that is **durably** attached to the document,
* an inked pharmacy stamp, which includes the date, plus a written annotation to indicate the medicine was supplied,
* an inked ‘Cancelled’ stamp to indicate that no further supplies are authorised in relation one or more medicines if the prescription (or copy) is to be returned to the patient (e.g. to facilitate further supplies of another medicine).

**Note:** A pharmacist is **not required** to separately mark electronic prescriptions, which comply with the Criteria for Electronic Prescriptions approved by the Secretary, because they should already be ‘marked’ electronically during the dispensing process.

# Retaining prescriptions for Schedule 8 medicines

Prescriptions (or prescription copies) for Schedule 8 medicines must be retained for 3 years and must be produced on demand to an authorised officer (regulation 64). These documents might represent evidentiary material and must therefore be stored in a manner that ensures their integrity.

* It is recommended that prescriptions are filed in chronological order in a container of a size that keeps them neatly in order.
	+ Placing the prescriptions haphazardly into a larger box will make it much more difficult for a pharmacist to locate specific prescriptions if required to do so.
* Some pharmacists prefer to use expanding files or file boxes and to sort prescriptions by names of medicines. This option may facilitate searches associated with discrepancies or make it easier to locate prescriptions to compare handwriting but, unless filing is carried out in a consistent manner, it may be more difficult to locate specific prescriptions when required to do so.
* Prescriptions should **not** be placed on a spike as this practice may damage key details of a prescription.
* It is recommended that retained prescriptions are neatly bundled and clearly labelled on a regular basis (e.g. monthly or quarterly) and stored securely at the pharmacy - **not** at another location.
	+ Storing retained prescriptions at another location would likely prevent producing them on demand.
* To enable prescriptions to be located when required, it is recommended that prescriptions associated with pharmacotherapy are stored separately from prescriptions for other Schedule 8 medicines.
* For **electronic prescriptions**, dispensing software **must include the functionality** to produce required prescriptions, on demand, without the pharmacist needing to seek to obtain a copy of a prescription from a third party.

**Note**: Victoria’s SafeScript database **does not**, in any way, impact the requirement for a pharmacist to be able to produce a prescription on demand.

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

GPO Box 4057

Melbourne 3001

Email: dpcs@health.vic.gov.au

Web: <https://www.health.vic.gov.au/public-health/medicines-and-poisons>

**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 submit your query using the [smart form](https://forms.business.gov.au/smartforms/landing.htm?formCode=mpr-enquiry) (<https://forms.business.gov.au/smartforms/landing.htm?formCode=mpr-enquiry>) or 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](https://www.health.vic.gov.au/drugs-and-poisons/documents-and-forms-to-print-or-download-medicines-and-poisons-regulation)’, 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 other categories of health practitioner:
	+ Medical practitioners, nurse practitioners, nurses and midwives, dentists (and other dental practitioners), optometrists (and orthoptists), podiatrists, and veterinary practitioners

## Other possible sources of information

### **Australian Health Practitioner Regulation Agency (Ahpra)**

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

**Pharmacy Board of Australia**

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

**Victorian Pharmacy Authority (VPA)**

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

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