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| Pharmacists |
| (Intervention and reporting requirements) |
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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) <https://www.health.vic.gov.au/public-health/medicines-and-poisons> 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.

# Pharmacists’ authorisation

Pharmacists are authorised to obtain, possess, use or supply scheduled poisons in the **lawful practice** of their profession (section 13 of the Act), including:

* supply of Schedule 4 and Schedule 8 poisons in accordance with the instructions of a health practitioner who is authorised to prescribe the medicine e.g. in accordance with a prescription, a chart instruction or an authorisation to administer.
* supply of a scheduled poison to a registered health practitioner (e.g. doctor’s bag order) or permit holder (e.g. Health Services Permit) who is authorised to obtain and possess the substance
	+ many practitioners are limited in relation to the drugs that they may possess, based on endorsements or conditions on their registrations
	+ in specific cases, pharmacists should examine the details of a practitioner’s registration (with Ahpra or the registration board) and/or the list of drugs that a specific category of practitioner is authorised to possess (by referral to the MPR website)
	+ permit holders could be required to produce copies of their current permits to demonstrate that they are currently authorised to obtain requested drugs
* supply (or administration) of Schedule 4 poisons, without a prescriber’s instructions, in certain circumstances e.g. emergency supply or continuation of supply (regulations 56 and 57), vaccinations (regulation 99)
* **retail** supply of Schedule 2 and Schedule 3 poisons in an open shop

A pharmacist’s authorisation does **not** authorise:

* the supply of Schedule 2 and Schedule 3 poisons, **by wholesale**, other than to persons who are authorised to purchase or obtain such medicines by wholesale (e.g. other pharmacists)
* the supply of Schedule 4 and Schedule 8 poisons to **health practitioners** who are not registered under the Health Practitioner Regulation National Law (i.e. registered in Australia) or who are not otherwise authorised to possess a particular substance.

# Interventions and contacting prescribers

Pharmacists should not dispense a prescription without satisfying themselves that it is safe, appropriate and lawful to supply the medicine. Findings by VCAT and the Pharmacy Board have repeatedly endorsed the view that this responsibility cannot be ignored simply because a prescription is presented.

The regulations require pharmacists to contact purported prescribers to:

* inform them that patients have obtained the same or a similar drug of dependence (Schedule 4 or Schedule 8) from another prescriber during the preceding eight weeks – see below for details
* authenticate prescriptions for Schedule 8 poisons – see below for details

In addition to complying with legislative requirements, pharmacists might need to contact prescribers to:

* check or confirm details or directions on prescriptions
* advise prescribers of contraindications and possible adverse reactions
* discuss the appropriateness of a particular course of treatment
* question the prescribed dosage or rate of administration

While the vast majority of prescriptions do not require an intervention, pharmacists must remain vigilant and assess each prescription (critically) before determining whether it is to be dispensed. The knowledge and experience of a pharmacist might be the only barrier to undesirable outcomes (inadvertent or intentional) and dispensary assistants cannot be expected to identify issues that pharmacists are trained to identify.

## Contemporaneous notes

In addition to records that are mandated by the regulations, it is strongly recommended that pharmacists make contemporaneous notes (in their dispensing records) of all communications with prescribers to demonstrate that they have complied with professional and regulatory responsibilities; to ensure that colleagues are aware whether notifications and communications have occurred; and to reduce the likelihood of false assumptions being made.

## Prescription-shopping patients

Pharmacists, who are presented with a prescription for a drug of dependence (Schedule 4 or Schedule 8) for a person for whom the same or a similar drug has been prescribed by a different prescriber during the previous 8 weeks, to take all reasonable steps **prior to supply** (or, if unable to do so, as soon as practicable after supply) to inform the prescriber that the previous supply has occurred (regulation 70) – unless the pharmacist has reason to believe that that prescriber is already aware of the previous supply or script (e.g. doctors **known** to be at the same clinic; or an indication on SafeScript that the relevant prescriber reviewed the profile prior to issuing a prescription).

# Forged and fraudulent prescriptions

Regulation 51(2) prohibits pharmacists from supplying a Schedule 8 poison on a prescription unless the prescription is handwritten; the pharmacist is familiar with the purported prescriber's handwriting **and** the writing on the prescription is comparable to the usual writing of the purported prescriber **or** the pharmacist has taken all reasonable steps to verify that the prescription was written by the purported prescriber. Where neither of these requirements can be met, a pharmacist may supply a quantity of a Schedule 8 poison sufficient for **not more than 2 days' treatment**.

**Note:**

* Regulation 51(2) applies to all prescriptions for Schedule 8 poisons; not only those prescriptions about which a pharmacist might be suspicious. Numerous fraudulent prescriptions have been dispensed because pharmacists did not comply with this regulation.
* Pharmacists **must not assume** that a prescription has been issued by an appropriately registered health practitioner simply because:
	+ it is a computer-generated prescription
	+ it is a PBS authority prescription
	+ it is approved by PBS online
	+ it is a hospital prescription
	+ similar prescriptions have been dispensed for the patient and are shown as dispensing events on SafeScript.
* Pharmacists who dispense electronic prescriptions, which **comply** with the Criteria for Electronic Prescriptions specified by the Secretary, are **not expected** to contact prescribers to verify the authenticity of the prescriptions.
	+ Pharmacists should still examine electronic prescriptions, critically, to ensure that supply of a Schedule 4 or a Schedule 8 poison **does not occur** upon a prescription that a pharmacist has **reason to believe** has beenforged or is fraudulent in any way.
	+ In the case of electronic prescriptions, this could include a person other than the prescriber accessing the prescribing software to create a fraudulent electronic prescription.

## Do not assume that a prescription is genuine

Forged and fraudulent **computer-generated** **prescriptions** are as prevalent as handwritten prescriptions and are often more difficult to identify; computer-generated forgeries fall into three main categories:

* Scanned copies or colour photocopies of genuine prescriptions
	+ These fraudulent prescriptions often lack the perforated edges that are evident on genuine prescriptions and can often be detected by careful examination.
* Forgeries that are printed with a PC using stolen prescription pages
	+ It is not uncommon for an offender to print their own phone number, on the otherwise blank computer-generated prescription, and arrange for an accomplice to answer the phone if called by a pharmacist
* Manual alterations to the quantity or number of repeats prescribed
	+ Medical practitioners are not authorised to make manual alterations to computer-generated prescriptions; the ‘Criteria for computer-generated prescriptions’ can be found on the MPR website and in Part 4 of the summary document for multiple categories of health practitioner.

### Pharmacists have been prosecuted

**Too many pharmacists** have dispensed forged or fraudulently altered prescriptions (sometimes on multiple occasions) in circumstances where, had they fulfilled their legislative responsibilities; examined the prescription critically; and/or examined the MPR website list of stolen prescriptions; the fraudulent prescriptions would have been identified.

Pharmacists might find it difficult to justify having dispensed forged prescriptions if they:

* fail to contact prescribers in circumstances where regulations 51 and/or 70 are applicable
* fail to contact prescribers where they might otherwise be expected to do so (e.g. excessive prescribing)
* fail to contact prescribers in relation to manually-altered computer-generated prescriptions or other non-compliant prescriptions, which might be fraudulently altered
* fail to contact MPR where section 32A of the Act is applicable (see “Excessive supply” below)
* rely upon the fact that the handwriting on one forged prescription is consistent with that of an earlier prescription, which was also a forged prescription
* fail to discover that a purported prescriber’s details had already been added to the list of stolen prescriptions on the frequently updated MPR website (see below).

The MPR website (in the ‘pharmacists’ section) contains:

* Current and recent alerts regarding significant and extensive cases of fraudulent prescriptions; historical examples of scams associated with fraudulent prescriptions; instructions for what to do after being presented with a fraudulent prescription; and advice regarding identifying fraudulent prescriptions.
* Tables of frequently updated details of ‘*Stolen and forged prescriptions*’, which enable pharmacists to search for names of prescribers whose prescriptions have been reported in relation to fraudulent and stolen prescriptions.
	+ It is strongly recommended that pharmacies have the MPR website bookmarked or listed as a favourite site, to facilitate prompt reference.

### Fraudulent prescriptions to be reported to MPR and police

Pharmacists must notify the police **and** MPR when they suspect or have reason to believe that a person has obtained **or attempted to obtain** Schedule 4 and Schedule 8 poisons by means of a false pretence (regulation 69).

* The presentation of forged or fraudulent prescriptions (whether or not the drugs were supplied) should be reported to MPR by completing and submitting the corresponding form, which can be located on the MPR website in the section for ‘online forms’.

# Excessive supply / reportable drug events

Section 32A of the Act requires a pharmacist **to** **notify MPR** in relation to a ‘reportable drug event’, e.g. when called upon to dispense or supply a Schedule 4 or Schedule 8 poisons for any person in greater quantities or more frequently than appears to be reasonably necessary.

* This requirement is applicable regardless of whether a prescription is a PBS Authority script, private prescription or is funded by another agency (e.g. TAC) **and** is not limited to supply on prescriptions.

Before notifying MPR, a pharmacist is expected to have communicated with the relevant prescriber/s to try to ascertain the reason for the apparently excessive quantities or frequency but, regardless of information provided, if the prescribing appears greater or more frequent than reasonably necessary, a pharmacist **must notify MPR** by completing and submitting the corresponding form, which can be located on the MPR website in the section for ‘online forms’.

## Key indicators of (possibly) excessive supply include:

* prescriptions for a quantity that exceeds the pharmacist’s previous experience (e.g. 48 testosterone injections or 80 sildenafil tablets would be expected to arouse suspicion)
* a prescribed dosage that significantly exceeds the normal therapeutic dose range
* a patient who **consistently** presents prescriptions or repeats more frequently than would be required if the medicine were taken in accordance with the noted directions.

**Other factors**, which might alert pharmacists or arouse suspicion, include:

* the continuous use of short-acting analgesics for management of chronic pain
* prescriptions for drugs with a “street value” (e.g. anabolic steroids, narcotics, alprazolam)
* repeated claims of lost prescriptions or misplaced medicines
* repeatedly deferring the supply of other medicines on the same prescription
* multiple pharmacies identified in SafeScript or PBS Safety Net information
* atypical behaviour (e.g. a person who explains too much, a medical practitioner collecting pethidine ampoules for a home visit, unusual phone calls from a purported prescriber that precede presentation of a prescription).

## Schedule 8 treatment permits

Pharmacists are **not** required to notify MPR simply because a Schedule 8 poison has been prescribed for a period greater than 8 weeks. It is the prescriber’s responsibility to obtain permits when required.

**Note**:

* Knowing (or believing) that a prescriber holds a Schedule 8 treatment permit is **not** sufficient reason to not notify MPR of apparently excessive prescribing as the prescribing might be in excess of permit limits.
* Pharmacists can review the SafeScript database to determine whether a prescriber holds a Schedule 8 treatment permit for a patient.
* A pharmacist who contacts a prescriber and discovers that the prescriber does not hold a permit; has no awareness of permit requirements; and/or does not realise that a medicine contains a Schedule 8 poison might question whether the noted prescribing is safe, appropriate or lawful.

The MPR website contains a document ‘*Schedule 8 permit requirements*’ (in the section for *Documents to print or download),* which may assist pharmacist and prescriber awareness of current permit requirements.

# Matters to be reported to MPR and/or police

Registered health practitioners are required to notify Victoria Police and/or MPR (as indicated below) when:

* a scheduled poison is lost by or stolen from them
	+ notify police **and** MPR (regulation 152)
* a discrepancy in records of transaction (e.g. Schedule 8 poison register) remains unresolved after the discrepancy has been investigated
	+ notify MPR **only** (regulation 112)
* records, required to be kept in relation to Schedule 4 or Schedule 8 poisons, are lost, stolen or destroyed
	+ notify MPR **only** (regulation 113)
* a person is suspected to have obtained, by means of a false pretence, an order or prescription for a Schedule 4 or 8 poison (regulation 26) or for a Schedule 3 poison that is a drug of dependence
	+ notify police **and** MPR (regulation 147)
* a person is suspected to have obtained, by means of a false pretence, a Schedule 4 or Schedule 8 poison (regulation 44) or a Schedule 3 poison that is a drug of dependence
	+ notify police **and** MPR (regulation 147)
* a person is suspected to haveobtained **or attempted to obtain**, by means of a false pretence (including the presentation of forged or fraudulently altered prescriptions), a Schedule 4 or Schedule 8 poison from a **pharmacist**
	+ notify police **and** MPR (regulation 69)

## How to notify MPR

The loss or theft of Schedule 4 and Schedule 8 poisons or discrepancies in records are requested:

* For holders of a **Health Services Permit**, to submit the ‘*Lost scheduled item form*’, which is available on the MPR website in the section for ‘*online forms’*
* For health practitioners, who are **not** employed by the holder of a Health Services Permit, to forward relevant details to the MPR email: dpcs@health.vic.gov.au

For fraudulent or fraudulently altered prescriptions, **pharmacists** are requested to submit the ‘*Notification of forged or altered prescription*’ form, which is available on the MPR website in the section for ‘*online forms’*.

For the loss or theft of prescription pads or prescription pages, other health practitioners are requested to submit the ‘*Notification of lost and stolen prescriptions*’ form, which is available on the MPR website in the section for ‘*online forms*’.

# 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 different health practitioner, a health practitioner may continue the treatment with medicines obtained from a wholesale supplier or by prescribing for self-administration.

# 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: <<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 forward your query (via e-mail: <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) <https://www.health.vic.gov.au/public-health/medicines-and-poisons> 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) <https://www.ahpra.gov.au/>

**Victorian Pharmacy Authority (VPA)**

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

**Pharmacy Board of Australia**

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

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