Managing Schedule 8 poisons

(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 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/>.

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 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.

Storage of Schedule 8 poisons

Schedule 8 poisons must be stored in a locked facility, fixed to the floor or wall, which provides not less security than a (10 mm thick) mild steel drug cabinet. Schedule 8 poisons must not be stored with any other items other than other drugs of dependence (regulation 74).

Expert advice received by the department indicates that fixing a drug cabinet to the floor or wall can be adequately achieved as follows:

- HARD CORE WALL: The cabinet to be secured by use of four (4) Loxin or Dyna Bolts, each 10mm by 50mm minimum.
- STUD AND PLASTER OR HOLLOW BLOCK: The cabinet to be secured by use of four (4) 10mm coach bolts through wall and through 3mm mild steel backing plate, which must, at minimum, be the same size as the back of the drug cabinet.

Larger or additional cabinets or safes must be obtained if existing storage facilities are insufficient to accommodate all Schedule 8 poisons. If a pharmacy lacks adequate capacity for storage of Schedule 8 poisons**, employed pharmacists** are strongly advised to inform the proprietor, in writing, and to retain documentary evidence that they have done so.

Keys to drug cabinets and safes must be strictly controlled to prevent unauthorised access and to reduce the likelihood of misappropriation. It is **not** acceptable to leave the key in the door of the cabinet or to keep it in a 'hidden' location where it might be located by persons other than pharmacists. These practices have contributed to misappropriation at some pharmacies.

Records of transactions in Schedule 8 poisons

Regulation 108 requires pharmacists, **as soon as practicable** after completing a transaction, to:

- make **true and accurate records** of all transactions in Schedule 8 poisons; and
- retain those records for 3 years; and
- produce them (on demand) to an authorised officer

Passwords

Pharmacists 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 of some complexity, which could not be easily guessed by another person.
- In multiple cases, since the advent of electronic registers, systematic misappropriation of Schedule 8 poisons has been concealed by creating false records in the names of other pharmacists because those pharmacists were merely using their initials as passwords.

Examples of non-compliance and what should be done

- Delaying the task of making a record in the drug register until it is more convenient is unlikely to satisfy the requirement to record transactions **as soon as practicable** unless the record is made on the same day as the transaction occurred.

  - The practice of delaying this task for days, weeks or months is unacceptable and is being increasingly dealt with by the Victorian Pharmacy Authority and, in some cases, by way of prosecution by MPR.
- Assuming that a 'calculated' balance is true and accurate **might not** satisfy the requirement to show the true and accurate balance of each Schedule 8 poison remaining after each transaction.
  - The accuracy of a calculated balance should be regularly confirmed as true and accurate in the drug register.
  - Some pharmacists do this by consistently ticking (or highlighting) a recorded balance or making separate line entries to indicate that the recorded balance has not been merely calculated.
- When Schedule 8 poisons are supplied and the prescriber is to forward the prescription subsequently, the pharmacist must record the transaction in the drug register when supply occurs, rather than delaying recording until the prescription is received.
- When only a portion of a prescribed quantity is supplied, the supplied portion is the quantity that must be recorded, with the supply of the remaining quantity to be recorded on a subsequent, corresponding occasion.
- Repeatedly recording a 'negative balance' is unacceptable.
  - A negative balance is unlikely to be acceptable other than where stock is received and supplied by the pharmacy at about the same time but the transactions were recorded in the wrong sequence.

Discrepancies in Schedule 8 register

Pharmacists must investigate discrepancies without delay (regulation 112).

- It is not acceptable to merely 'correct' the recorded balance without resolving the discrepancy or without clearly recording how the discrepancy was resolved.
- Discrepancies that cannot be resolved must be reported to MPR; details to be forwarded by email to dpcs@dhhs.vic.gov.au

Responsibilities of individual pharmacists

Each pharmacist is required to record the true and accurate balance after each transaction. Any pharmacist who records an incorrect balance has contravened the regulations, regardless of whether the incorrect balance was due to calculations involving previous recording errors by other pharmacists.

Whilst non-compliance or errors by other pharmacists can be a major factor in creating, perpetuating and compounding discrepancies, individual pharmacists must take action when they identify discrepancies between recorded and actual balances when dispensing Schedule 8 poisons. They are advised to:

- record the true and accurate balance in the register
- identify the discrepancy prominently in the register
- investigate and make a meaningful attempt to resolve the discrepancy
- record an explanation where a discrepancy is resolved
- if the discrepancy cannot be resolved, report the matter to the proprietor or pharmacist-in-charge and/or **ensure** that MPR is notified in accordance with regulation 112
  - to demonstrate compliance with regulation 112, it is recommended that all relevant actions are documented, possibly in the drug register

Destruction of Schedule 8 poisons

Regulation 115 authorises pharmacists to destroy Schedule 8 poisons in the presence of a witness who is a dentist, medical practitioner, pharmacist, veterinary practitioner, nurse or midwife.

All destructions must be recorded in the Schedule 8 register. Details must include the date of destruction; drug name and strength; quantity destroyed; reason for destruction; the name of the pharmacist responsible for the destruction plus the name of the witness.

Using a separate register or designated page/s of the drug register to record, “Drugs for Destruction”, is a practice that often proves valuable in accurately accounting for returned or expired drugs.

Returned and unwanted medicines (RUM)

The National Return and Disposal of Unwanted Medicines Project (NatRUM) is a Commonwealth funded program, providing all community pharmacies in Australia a method of environmentally safe disposal of unwanted and expired medicines returned to the pharmacy by the consumer.

- For more information and details of the NatRUM protocols for pharmacists, please refer to the Return Unwanted Medicines website <https://returnmed.com.au/>.

Pharmacists should take all reasonable steps to ensure any Schedule 8 poison returned for disposal is recorded and destroyed in accordance with regulations.

- It is not acceptable to place a bag of returned medicines into the RUM bin without examining the contents to determine whether Schedule 8 poisons are contained therein – unless there is an obvious risk to personal safety.

RUM bins and their role in destroying Schedule 8 poisons

Where a pharmacist is **merely** initiating the destruction of a Schedule 8 poison, which is intended for subsequent high-temperature incineration (e.g. via RUM bins), the Schedule 8 poison must be rendered unidentifiable and unrecoverable to prevent it being retrieved from the RUM bin, as has occurred on several occasions at multiple pharmacies.

If liquids are to be placed into the RUM bin, an absorbent substrate (e.g. kitty litter) should be used.

Misappropriation of drugs of dependence

In recent years, MPR has investigated pharmacies in relation to misappropriation and/or unlawful diversion of significant quantities of Schedule 8 poisons including cocaine, dexamphetamine, methylphenidate, morphine, methadone, pethidine, oxycodone and alprazolam plus other drugs of dependence (e.g. diazepam, testosterone and other anabolic steroids) plus analgesics containing codeine). Offenders have been identified as pharmacists as well as dispensary technicians and other (previously) trusted staff members.

Lack of adequate supervision or inventory control by pharmacists and non-compliance with regulations, relating to maintaining contemporaneous and accurate records plus investigating discrepancies and reporting unresolved discrepancies, were often contributing factors in enabling offenders to misappropriate drugs for many months (or years) without detection.

Offending pharmacists have been found to have tried to conceal their activities by:

- creating false records of prescriptions or drugs purportedly supplied to other pharmacies
- ordering Schedule 8 poisons but not recording receipt of the drugs in the drug register
- falsely recording the destruction or spillage of Schedule 8 poisons
- creating forged prescriptions or fraudulent repeat authorisations
- failing to record Schedule 8 poisons that were returned to the pharmacy for destruction

Misappropriation by other staff has sometimes involved ordering drugs of dependence and removing corresponding invoices; or deleting, amending and manipulating inventory records. **Note**: Delegation of duties

to (trusted) employees does not relieve pharmacists of their responsibilities to prevent unauthorised access to Schedule 4 and Schedule 8 poisons; pharmacies should have procedures in place to deter misappropriation and to detect it promptly, should it occur.

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> 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

Victorian Pharmacy Authority (VPA)

Web: www.pharmacy.vic.gov.au

Pharmacy Board of Australia

Web: www.pharmacyboard.gov.au

To receive this document in another format, phone 1300 364 545, using the National Relay Service 13 36 77 if required, or email dpcs@health.vic.gov.au

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.