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| Schedule 2 and 3 poisons (OTC medicines) |
| 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 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.

# Over-the-counter medicines (OTC)

Medicines described as ‘over-the-counter’ medicines will fall into one of the following categories:

* **Unscheduled** preparations, which are available from any number of retail outlets (e.g. convenience stores, supermarkets and pharmacies)
* **Schedule 2 poisons** (labelled ‘Pharmacy Medicine’), which are predominantly available from pharmacies so that supplies are carried out under the supervision of a pharmacist, who is available to provide professional advice in relation to the use of the medicine.
* **Schedule 3 poisons** (labelled ‘Pharmacist Only Medicine’), which are also available from pharmacies but which are subject to more stringent regulatory controls than Schedule 2 poisons, including the personal involvement of a pharmacist who is required to take ‘all reasonable steps’ to ensure there is a therapeutic need for the medicine.

## Supply in an open shop prohibited – other than by pharmacists

Schedule 2 and Schedule 3 poisons must not be supplied by in an open shop, other than by pharmacists (section 13 of the Act).

However, registered health practitioners who are authorised to supply (any or some) scheduled poisons might be authorised to supply Schedule 2 and Schedule 3 poisons in the lawful practice of their professions.

## Schedule 2 and Schedule 3 medicines in larger quantities

The poisons schedules of various medicines are directly related to the number of doses contained in a particular pack size and, sometimes the manner in which the medicine is packaged and labelled.

In some cases a larger pack size will cause a medicine to be subject to the stricter regulatory controls of a higher schedule. It is recommended that the stricter regulatory controls are applied when a person wishes to obtain multiple smaller packs in circumstances where a larger pack, containing a comparable number of doses, would place the medicine in a higher schedule.

## Supplying multiple packs

The Australian Medical Association (AMA) has expressed concerns about pharmacists who offer discounts for multiple packs of Schedule 2 and Schedule 3 poisons. The AMA suggests that this practice does not encourage sensible use or regular review with a health practitioner. The practice is of particular concern when it involves medicines that are subject to misuse and abuse (e.g. cough mixtures, analgesics, preparations containing pseudoephedrine, Unisom® gel capsules) or medicines that are likely to cause adverse reactions if used excessively (e.g. ibuprofen and codeine).

### Trafficking

A pharmacist who supplied multiple packs of ‘over-the-counter’ medicines containing pseudoephedrine was successfully prosecuted for trafficking a drug of dependence; the cumulative total of pseudoephedrine supplied exceeded the amount that corresponds to a traffickable quantity.

# Supply by wholesale likely to be unlawful

Health practitioners (including pharmacists) are not authorised to sell or supply Schedule 2 or Schedule 3 poisons by wholesale unless specifically authorised to do so. The definition of ‘wholesale’ includes sale or supply ‘for the purposes of resale or supply to another person’. Therefore, it is unlawful for health practitioners to sell or supply Schedule 2 or Schedule 3 poisons to persons who intend to sell or supply them from retail outlets.

Similarly, it is unlawful for health practitioners to sell or supply Schedule 2 or Schedule 3 poisons in quantities that clearly exceed a quantity that could be considered a retail quantity (e.g. supplying bulk quantities to overseas markets).

Pharmacists are specifically authorised to supply Schedule 2 and 3 poisons to other pharmacists in the lawful practice of their profession and on the order of a permit holder or health practitioner who is authorised to obtain the medicine.

Otherwise, only holders of appropriate licences (issued by MPR) are authorised to sell or supply Schedule 2 or Schedule 3 poisons, by wholesale, and then only to persons who are expressly authorised to obtain Schedule 2 and Schedule 3 poisons, by wholesale. There are also TGA regulations, which restrict the sale of therapeutic goods to international markets without the expressed approval of the sponsor/manufacturer of the product.

# Prescribing and supplying Schedule 3 poisons

Schedule 3 poisons have a greater potential for misuse or abuse than Schedule 2 poisons. Accordingly, the supply of Schedule 3 poisons is subject to regulations which require the personal involvement of a registered health practitioner (usually a pharmacist) to exercise competent professional judgement in assessing both the appropriateness of the medicine and the quantity that is to be supplied in addition to providing professional advice about the safe and effective use of the medicine (regulations 134 to 141).

With the exception of supply by pharmacists, presented with a prescription, health practitioners who are authorised to supply (or prescribe) a Schedule 3 poison are required to observe the following requirements.

## All reasonable steps

Where the regulations require health practitioners to take ‘all reasonable steps’ (e.g. to ensure there is a therapeutic need); 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 that another member of the corresponding profession would take 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 requests that they do so. Registered health practitioners are strongly advised to read another document in this series, ‘All reasonable steps and other key terms’ to gain a greater understanding of how compliance might be achieved.

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 and should be wary when issuing a prescription for an unfamiliar medicine.

**Note**:

* Fulfilling the requirement to take ‘all reasonable steps’ to ensure there is a therapeutic need is likely to be difficult to demonstrate if Schedule 3 poisons are supplied in a quantity that exceeds a quantity that might be needed for personal therapeutic use.

### Recording supplies of Schedule 3 poisons

There is no mandatory recording requirement for the supply of a Schedule 3 poison. However, in order to take ‘all reasonable steps’ to ensure a therapeutic need exists (where there is reason to believe a Schedule 3 poison might be misused, abused or used excessively), a supplier should make a record, similar to the record required for Schedule 4 poisons, so that frequency of use may be reviewed if further supplies are sought,

### Remote requests for Schedule 3 poisons

Unless a health practitioner has already taken the necessary steps to ensure a particular person has an existing therapeutic need, Schedule 3 poisons must not be supplied in response to requests forwarded by correspondence or via the internet.

## Drugs of dependence

A health practitioner who supplies a Schedule 3 poison, which is classified as a drug of dependence, is also required to take ‘**all reasonable steps**’ to ascertain the identity of the person who is to be treated.

## Directions and labelling

A health practitioner who supplies a Schedule 3 poison must:

* personally deliver or personally supervise its delivery to the person; and
* provide directions for the use of the Schedule 3 poison; and
* place a label on the container which uniquely identifies the supplier

**Note:**

* The preceding requirement does not apply to a pharmacist who supplies a Schedule 3 poison in accordance with a prescription or chart instruction or, by wholesale, in circumstances where a pharmacist is specifically authorised to supply, by wholesale (see pages 2 and 3).
* To ensure a person has a clear understanding of verbal directions for the use of a Schedule 3 poison, it might be necessary to affix a dispensing label, similar to that used to label a Schedule 4 poison. In doing so, the requirement to uniquely identify the supplier might also be achieved.

## First Aid Kits and other Emergency Use

A pharmacist may supply a Schedule 3 poison (other than a drug of dependence) for use in a life threatening emergency where it is anticipated the end user may not be under the care of the pharmacist (regulation 141(1)(b)). This regulation enables supply of a Schedule 3 poison for inclusion in a first aid kit, e.g. in a school, workplace or other community organisation.

Examples of Schedule 3 poisons deemed relevant to treatment in a life threatening emergency are epinephrine (EpiPen®) for treatment of anaphylaxis, salbutamol for treatment of asthma and other breathing problems, and naloxone for opioid overdose.

**Note**: This provision does not authorise pharmacists to supply Schedule 3 poisons, by wholesale, to manufacturers or wholesale suppliers of first aid kits.

# Storage and display of Schedule 3 poisons

Notwithstanding other regulatory requirements, regulation 143 makes it an offence to store or display any Schedule 3 poison in a manner that will allow self-selection by the public or in a manner that will promote the sale or draw undue attention to it. Display material that promotes a price discount for multiple packs of a Schedule 3 poison is likely to be considered unacceptable, unlawful or professionally irresponsible.

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

GPO Box 4057

Melbourne 3001

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](mailto: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:
  + 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:

## Other possible sources of information

### Australian Health Practitioner Regulation Agency (Ahpra)

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

### Veterinary Practitioner Registration Board of Victoria

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

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