

# Key legislative requirements for veterinary practitioners

## Scheduled poisons

This summary has been prepared by Drugs and Poisons Regulation (DPR) to assist veterinary practitioners in understanding their obligations under the legislation. **Note:** For easier reading and comprehension, this summary does not include the many and varied options that are covered by the legislation; it focuses on circumstances that are applicable to the majority of veterinary practitioners. Please refer to the Drugs, Poisons and Controlled Substances Act 1981 (the Act) and Regulations 2006 (at [www.legislation.vic.gov.au](http://www.legislation.vic.gov.au)) for full details.

### Obtaining Schedule 4 or Schedule 8 poisons

Licensed wholesalers or pharmacists must **only** supply drugs to an authorised person. Their records **must** therefore identify the authorised person (e.g. veterinary practitioner) by name regardless of to whom an invoice for payment might be directed (e.g. veterinary clinic, service company).

### Authorisation of veterinary practitioners

Veterinary practitioners are authorised to obtain, possess, use or supply **most** drugs and poisons for the **lawful practice** of their profession, i.e. for the veterinary **treatment of animals under their care** (section 13 of the Act, regulation 13).

A veterinary practitioner is **not** authorised to obtain drugs for personal use or for use by any other person (e.g. spouse or employees) or to sell or supply drugs or poisons by wholesale (including to other veterinary practitioners) – an activity for which a Drugs & Poisons licence is required (section 23 of the Act).

Self-administration of Schedule 4 and Schedule 8 poisons is **prohibited** unless the drugs have been lawfully prescribed and supplied by a registered health practitioner (e.g. medical practitioner) or supplied by a pharmacist upon presentation of a prescription from a registered health practitioner (regulation 48). **Note:** This does **not** mean that, where drugs have been prescribed by another health practitioner, a veterinary practitioner may continue the treatment with drugs obtained from a wholesale supplier.

### Storage requirements

**Schedule 8 poisons** (labelled Controlled Drug) are drugs with more strict legislative controls, e.g. codeine phosphate, morphine, pethidine, oxycodone, flunitrazepam, fentanyl, butorphanol (Dolorex<sup>®</sup>), buprenorphine (Temgesic<sup>®</sup>), methadone (Physeptone<sup>®</sup>) and ketamine.

- Schedule 8 poisons must be stored in a locked facility, fixed to the floor or wall, and providing not less security than a (10 mm thick) mild steel drug cabinet **and** must not be stored with any other items (e.g. money) other than other drugs of dependence.
- When **transported** for use in another location, **Schedule 8 poisons** must be stored in a locked receptacle (e.g. toolbox) in the veterinary practitioner's possession. If the receptacle is necessarily out of the veterinary practitioner's possession (even for a brief period), it should be secured, out of sight, in a lockable facility (e.g. locked vehicle or locked cupboard) to prevent unauthorised access.

**Schedule 4 poisons** (Prescription Only Medicine or Prescription Animal Remedy) include other drugs for which prescriptions are required, e.g. cardiovascular drugs, antibiotics & many others.

- Schedule 4 poisons (including professional samples) must be stored in a lockable storage facility. (e.g. cupboard, drawer, fridge, filing cabinet, drug store, treatment room).

**Drugs of dependence** is a term used to describe all Schedule 8 poisons and specified Schedule 4 poisons that are subject to misuse and trafficking, e.g. benzodiazepines, dextropropoxyphene, anabolic steroids.

- **Schedule 4 drugs of dependence** may be stored in the same manner as other Schedule 4 poisons **or** in the drug cabinet with Schedule 8 poisons.

**Schedule 2 and 3 poisons** (labelled Pharmacy Medicine or Pharmacist Only Medicine respectively) must only be supplied (in an open shop) by pharmacists (section 13(2) of the Act).

- Veterinary practitioners may use or supply Schedule 2 and Schedule 3 poisons in a manner similar to Schedule 4 poisons (i.e. for the treatment of animals under their care) but must **not** supply these drugs for human use (including clinic staff).
- To prevent unlawful supply, it is recommended that Schedule 2 and Schedule 3 poisons are stored and handled in a manner similar to Schedule 4 poisons.

**Schedule 5 and 6 poisons** (labelled Caution and Poison respectively) may be sold by retail in an open shop or the reception area of a veterinary practice in the manufacturers' unopened primary packs.

**Schedule 7 poisons** (labelled Dangerous Poison) must be stored in a manner that prevents public access and must be supplied only to persons at least 18 years of age, with full details of each transaction recorded (sections 38 and 40 of the Act).

## Access to Schedule 4 and Schedule 8 poisons

Storage facilities for Schedule 4 and Schedule 8 poisons must be secured to prevent access by all persons **not** authorised under the legislation (e.g. staff other than a veterinary practitioner) unless the veterinary practitioner is present. Accordingly, keys should not be accessible to unauthorised staff members.

Staff members may be left in possession of Schedule 4 and Schedule 8 poisons in the following circumstances:

- Drugs may be left with a veterinary nurse (in order to administer the drugs to a specific animal at the clinic) in accordance with instructions for administration for the specific animal. The veterinary nurse is **not** authorised to supply such drugs to the owner of the animal or the owner's agent – except as stated below.
- An employee of the clinic may possess drugs that have been lawfully prepared for supply and labelled (see below) by the veterinary practitioner for delivery to, or collection by a person - provided the drugs are in a sealed package that clearly identifies the animal or the animal's custodian to whom they are to be supplied.

## Under the care of a veterinary practitioner

Guidelines, prepared by the Veterinary Practitioners Registration Board of Victoria, reiterate the regulatory requirement that, before prescribing, administering or supplying a Schedule 4 or Schedule 8 poison, a veterinary practitioner must take **all reasonable steps** to establish the therapeutic need of an animal and should document the clinical justification of that need in the veterinary medical record.

The Guidelines also indicate that, before an animal or herd could be considered to be under a practitioner's care, the following conditions should be met:

- the practitioner should have been given responsibility for the health of the animal or herd in question by the owner or the owner's agent; and
- the care of the animal or herd by the practitioner should be real and not merely nominal (i.e. there must be evidence of personally having contact with the animal/herd for diagnosis and treatment and of assuming responsibility for the diagnosis, treatment and outcome); and

- the practitioner must have a thorough knowledge of the current health and treatment status of the animal or herd by having:
  - seen the animal or herd for the purpose of diagnosis and establishing a therapeutic need immediately prior to supplying a drug; or
  - visited the premises where the animal or herd is kept sufficiently often and recently enough to have acquired from, personal knowledge and inspection, an accurate picture of the current health state on that premises sufficient to enable the making of a diagnosis and to establish a therapeutic need.

## Supplying Schedule 4 or Schedule 8 poisons

Veterinary practitioners may supply Schedule 4 and Schedule 8 poisons for the veterinary treatment of animals under their care.

Veterinary practitioners who supply Schedule 4 or Schedule 8 poisons must personally ensure the correct drug is selected, labelled and packed in the required manner. This responsibility **cannot** be delegated to another person.

When supplied, Schedule 4 and Schedule 8 poisons must be **labelled** in accordance with the provisions of regulation 29, including - the name of the owner or person having custody of the animal; the name or species of the animal; the date on which the transaction is recorded; the name, address and telephone number of the veterinary clinic; the name of the poison or controlled substance or a trade name that unambiguously identifies the poison or controlled substance and its strength, form (e.g. tablets, capsules) and quantity; plus directions for use. **Note:** An exemption might apply for bulk supplies for treating flocks or herds of animals (see below).

**Containers** of scheduled poisons must be impervious to the contents, sufficiently sturdy to prevent leakage and capable of being securely re-closed. Labels should be attached securely in a manner that does not obscure essential information on the container.

## Related issues

Veterinary practitioners, who supply Schedule 4 and Schedule 8 poisons, may be required to demonstrate (through their records) that they have taken all reasonable steps to ensure a therapeutic need and that treated animals were 'under their care'.

With this in mind, veterinary practitioners should consider whether they are able to justify supplying veterinary medicines without having had recent interaction with a client or on the basis of a client's capacity to assess and determine the therapeutic need of an animal.

Veterinary practitioners must not enter into arrangements whereby they serve merely as the suppliers of veterinary medicines who rely on clients or agents to fulfil the responsibilities of a registered veterinary practitioner.

The practice of supplying veterinary medicines to clients, directly or via an intermediary (e.g. an AI technician) is likely to be unlawful if veterinary practitioners fail to take all reasonable steps to ensure there is a therapeutic need; fail to satisfy the requirement of treating only animals under their care; fail to label containers or provide the written advice required by the legislation; or fail to accurately record transactions.

## Treating flocks or herds of animals

Whilst the DPCS Regulations, do not require a veterinary practitioner to label each container of a Schedule 4 poison that is supplied in bulk for the treatment of flocks or herds of animals, provided that—

- each container of the poison retains the manufacturer's original label; and
- the veterinary practitioner provides written instructions containing the information specified in regulation 29 to the owner of, or the person having custody of, the animals,

the Agricultural and Veterinary Chemicals (control of use) Regulations require all containers to be labelled.

Furthermore, when supplying drugs for flocks or herds, it is government policy that while directions and other details may be supplied on an advice note, details of the veterinary practice, the name of the owner of the animals, the species and the date of supply should be included on the label on each container.

## Records of transactions

A veterinary practitioner **must** make true and accurate records of all drugs administered or supplied, retain them for 3 years and produce them, on demand, to an authorised officer of the department.

An animal's treatment record (computerised or manual) showing the client's name and address, date of the transaction, identity of the veterinary practitioner providing the treatment, directions for use and details of the drug administered or supplied may be sufficient for **Schedule 4 poisons** but for **Schedule 8 poisons** a separate record (almost certainly manually created) is also required.

Records for Schedule 8 poisons must be in a form that shows the true balance remaining after each transaction (received and supplied) and that cannot be altered without detection. **Note:** A drug register or administration book is usually available from wholesalers. Where the use of Schedule 8 poisons is limited, a smaller book may be available from the Royal Australian College of General Practitioners.

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The following section of this summary has been prepared, following consultation with officers from the Department of Primary Industries, to assist veterinary practitioners who treat food-producing animals.

## Treating food-producing animals

The use of veterinary medicines in food producing animals is governed by the Agricultural and Veterinary Chemicals (Control of Use) Act 1992 and the Regulations of 2007, whilst the importation, evaluation, registration and labelling of agricultural and veterinary chemical products up to the point of supply is governed by the Agricultural and Veterinary Chemical Code Act of Victoria 1994.

Veterinary practitioners who supply Schedule 4 poisons for the treatment of food-producing animals should ensure that they are familiar and comply with all relevant requirements of the Control of Use legislation including withholding periods, animal identification, advice notices and appropriate labelling. Veterinary practitioners must also ensure that clients are aware and are provided with documented information relating to Withholding Periods (WHP) and Export Slaughter Intervals where the information is available.

In addition to the requirements previously stated in this document, the labels on containers or advice notes for food-producing animals must identify the type (breed, age and sex) or identification number of the animals. The WHP for the species of animal or the statement 'Nil Withholding Period' must also be included.

Veterinary practitioners providing off-label or unregistered treatments must also include the WHP on the label or advice note to ensure any drug residues are below the Maximum Residue Level (MRL) indicated on the Australian Pesticides and Veterinary Medicines Authority (APVMA) website for the particular drug in the particular animal or, if no MRL is available, that the WHP is sufficient to ensure there will be no residues present at the time an animal is slaughtered for food consumption.

Drugs that have not been registered by the **Australian** Pesticides and Veterinary Medicines Authority should only be used to treat single animals.

Drugs, which are labelled 'Do not Use in Food Producing Animals', must not be used, even for the treatment of single animals.

The APVMA residue website can be found at: [www.apvma.gov.au/residues/index.php](http://www.apvma.gov.au/residues/index.php)

Additional requirements, relating to the use of anabolic and androgenic steroids and other veterinary chemicals, can be found on the Department of Primary Industries website under the heading 'Veterinary Chemicals' at:

<http://new.dpi.vic.gov.au/agriculture/farming-management/chemical-use>

## Records

In addition to the requirements previously stated, veterinary practitioners are required to record the location of an animal (i.e. the farm address and a shed and/or pen number for intensively housed animals), the amount of product supplied or used, the name, active constituent, concentration and form of unregistered products, the species of animal treated or to be treated and the withholding period information that is provided to the client.

## For further information

<p><b>Department of Health (DH)</b></p> <p><b>Drugs and Poisons Regulation</b></p> <p>GPO Box 4541 Melbourne 3001</p> <p>Phone: 1300 364 545 Fax: 1300 360 830 Web: <a href="http://www.health.vic.gov.au/dpu">www.health.vic.gov.au/dpu</a></p>	<p><b>Veterinary Practitioners Registration Board of Victoria</b></p> <p>Level 11 470 Collins St Melbourne 3000</p> <p>Phone 9620 7444</p>	<p><b>Department of Primary Industries (DPI)</b></p> <p><b>Plant Biosecurity and Product Integrity</b></p> <p>475 – 485 Mickleham Road Attwood 3049</p> <p>Phone <b>136 186</b></p>
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