

Veterinary practitioners

Key legislative requirements in Victoria

Explanatory notes

The legislation that defines lawful actions in relation to scheduled poisons is contained in the Drugs Poisons and Controlled Substances Act 1981 (the Act) and the Drugs Poisons and Controlled Substances Regulations 2017 (the regulations). The regulations complement the Act by authorising actions that would otherwise be unlawful and define the outcomes required of lawful actions. For full details of legislative requirements, current versions of the Act and the regulations should be considered in concert and not read in isolation. These documents can be accessed at Victorian Law Today (www.legislation.vic.gov.au). A link to the Poisons Standard, which contains details relating to poisons schedules plus labelling and packaging requirements, can be found on the DPR website (at www2.health.vic.gov.au/dpcs).

This document has been prepared by Drugs and Poisons Regulation (DPR) to assist veterinary practitioners to understand key professional and legislative requirements. For simplicity of reading, it does not include the many and varied options that are covered by the legislation. It focuses on information that is relevant to the majority of practitioners within corresponding categories and does not include references to Schedule 9 poisons. Documents relating to other key requirements and practitioners can be located on the DPR website (at www2.health.vic.gov.au/dpcs).

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 medication to a person's body (or personally observe its introduction).
- **'Supply'** means to provide a medication to be 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 medication but the supply might not occur until a later time. 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 to the Act, which are known to be subject to misuse and trafficking. The term is not limited to Schedule 8 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).

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 (section 13 of the Act), i.e. for the veterinary treatment of animals under their care.

A veterinary practitioner is **not** authorised to obtain drugs for personal use or for use by any other human (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 wholesale licence is required (section 23 of the Act).

Note: Licensed wholesalers and pharmacists must **only** supply drugs to an authorised person. Suppliers' 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).

Prescribing or supplying Schedule 4 and Schedule 8 poisons

Veterinary practitioners must **not** prescribe or supply Schedule 4 or Schedule 8 poisons other than for the **veterinary treatment** of animals **under their care** and then only after taking **all reasonable steps** to ensure that a therapeutic need exists (regulations 19 and 38).

Guidelines, prepared by the Veterinary Practitioners Registration Board of Victoria, provide further clarification about what is meant by 'under their care'.

'Under their care'

The Guidelines 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 must 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.

'All reasonable steps'

To understand the meaning and application of the important term '**all reasonable steps**', veterinary practitioners are advised to read the corresponding health practitioner document on the DPR website: 'All reasonable steps and other key terms' (see following page).

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 only 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.

Key documents on the DPR website

The DPR website (www2.health.vic.gov.au/dpcs in the section for *Documents to print or download – registered health practitioners*) contains summaries of legislative requirements 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 records
 - Prescribing
 - Handwritten and computer-generated prescriptions
 - **All reasonable steps** and other key terms
 - Schedule 2 and 3 poisons
- Summaries relating to other individual categories of health practitioner:

Storage of Schedule 4 and Schedule 8 poisons

The regulatory requirements for storage of Schedule 4 and Schedule 8 poisons are detailed and explained in the health practitioner document: 'Possession and storage'.

Records of transactions

The regulatory requirements for recording administration and supply of scheduled poisons are detailed and explained in the health practitioner document: 'Supply, administration and records'.

Required components of prescriptions

The regulatory requirements for components of handwritten and computer-generated prescriptions are detailed and explained in the health practitioner document: 'Handwritten and computer-generated prescriptions'.

Labelling dispensed medicines

Veterinary practitioners 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 section 1.5.6 plus Appendices L and K); a link to the Poisons Standard is located on the DPR website (at www2.health.vic.gov.au/dpcs) in the "Related sites" section.

Required components of a label for a dispensed veterinary medicine include the following:

- 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 medication 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
- the date on which supply is made or the dispensing is recorded (unless that date is clear from the dispensing 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, address and telephone number of the practitioner supplying the medicine
- as the poison 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
 - the words “FOR ANIMAL TREATMENT ONLY”

Containers 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.

Treating flocks or herds

The DPCS Regulations previously contained an exemption to labelling requirement where a veterinary practitioner supplied multiple containers for the treatment of flocks or herds of animals. **This is no longer the case**; the Agricultural and Veterinary Chemicals (Control of Use) Regulations require all containers to be labelled.

Destruction of Schedule 8 poisons

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

Self-administration

Self-administration of a Schedule 4 or Schedule 8 poison is **prohibited** unless the drug has been lawfully prescribed **and** supplied by a registered health practitioner (e.g. medical practitioner) or supplied by a pharmacist on a prescription from a registered health practitioner (regulation 105).

Note: This does **not** mean that once a drug is prescribed by a registered health practitioner, a veterinary practitioner may continue the treatment with drugs obtained from a wholesale supplier.

Over-the-counter medicines and poisons

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

Veterinary practitioners may use or supply Schedule 2 and Schedule 3 poisons in a similar manner to Schedule 4 poisons, i.e. for the treatment of animals under their care. However, Schedule 2 and Schedule 3 poisons must not be supplied for any other purpose or to any other person. Note: To prevent inadvertent 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).

Treating food-producing animals

The following section of this document was prepared, following consultation with officers from the Department of Environment and Primary Industries, to assist veterinary practitioners who treat 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. The importation, evaluation, registration and labelling of agricultural and veterinary chemical products up to the point of supply are governed by the Agricultural and Veterinary Chemical Code Act of Victoria 1994.

Withholding periods and related requirements

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 of 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.

Unregistered products

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 APVMA should only be used to treat single animals.

Drugs that 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: <http://apvma.gov.au/node/10806>

Additional requirements relating to the use of anabolic and androgenic steroids and other veterinary chemicals can be found on the Agriculture Victoria website under the heading 'Veterinary Chemicals' at: <http://www.depi.vic.gov.au/agriculture-and-food/farm-management/chemical-use/veterinary-chemicals>

Additional recording requirements

In addition to the requirements of the DPCS Regulations, veterinary practitioners are required to record the location of food-producing animals (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

Department of Health & Human Services (DHHS)

Drugs and Poisons Regulation

GPO Box 4057
Melbourne 3001

Tel: 1300 364 545

Fax: 1300 360 830

Email: dpcs@dhhs.vic.gov.au

Web: www2.health.vic.gov.au/dpcs

Other possible sources of information

Veterinary Practitioners Registration Board of Victoria

Web: www.vetboard.vic.gov.au

Department of Environment and Primary Industries (DEPI)

Plant Biosecurity and Product Integrity

Web: www.depi.vic.gov.au

Phone 136 186

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