

# Guide to Poisons and Therapeutic Goods Legislation for Veterinary Surgeons



This Guide is a summary only. For complete details, reference should be made to the *Poisons and Therapeutic Goods Act 1966* and the *Poisons and Therapeutic Goods Regulation 2002* (obtainable from the NSW Government Information Service Bookshop at the Goodsell Building, 55 Hunter St., Sydney, Phone (02) 9238 0950, Fax (02) 9228 7227).

Further information may be obtained from the Duty Pharmaceutical Adviser, Pharmaceutical Services Branch, NSW Department of Health, P. O. Box 103, Gladesville, 1675. Phone: (02) 9879 3214. Fax: (02) 9859 5165.

## The Poisons List:

The Poisons List is the list of substances to which the Poisons and Therapeutic Goods Act and Regulation apply. It consists of eight schedules (Schedule 1 is empty, so reference to it has been omitted), according to a pattern which is uniform in most respects throughout Australia, as follows:

### Schedule 2:

Substances which are dangerous to life if misused or carelessly handled, but which should be available to the public for therapeutic use or other purposes without undue restriction.

May be supplied only by medical practitioners, authorised nurse practitioners, pharmacists, dentists, veterinary surgeons or persons licensed to sell poisons.

### Schedule 3:

Substances which are for therapeutic use and:

- (i) about which personal advice may be required by the purchaser in respect of their dosage, frequency of administration and general toxicity;
- (ii) with which excessive unsupervised medication is unlikely; or
- (iii) which may be required for use urgently so that their supply only on the prescription of a medical practitioner or veterinary surgeon would be likely to cause hardship.

Schedule Three substances may be supplied only by medical practitioners, authorised nurse practitioners, pharmacists, dentists or veterinary surgeons. Where such substances are supplied by a pharmacist, they must be personally handed to the patient by the pharmacist. Additional conditions may apply. Similarly, a veterinary surgeon should be personally and directly involved in the supply of any Schedule 3 preparation.

### Schedule 4 (Restricted Substances):

Substances which in the public interest should be supplied only by a medical practitioner, authorised nurse practitioner, dentist or veterinary surgeon, or by a pharmacist on the written prescription of a medical practitioner, authorised nurse practitioner, dentist or veterinary surgeon.

### Schedule 5:

Poisonous substances of a dangerous nature commonly used for domestic purposes which should be readily available to the public but which require caution in their handling, use and storage.

### Schedule 6:

Substances which should be readily available to the public for agricultural, pastoral, horticultural, veterinary, photographic or industrial purposes or pest destruction.

### Schedule 7:

Substances of exceptional danger which require special precautions in their manufacture or use.

### Schedule 8 (Drugs of Addiction):

Substances which are addiction producing or potentially addiction producing. Possession, supply, prescribing and use are strictly limited.

Provision is also made for substances to be rigidly controlled by subjecting their use or supply to special authority.

### Schedule classification:

Preparations classified as restricted substances (S4) or drugs of addiction (S8) are available for animal use on veterinary authority only, regardless of whether or not they are registered as stock medicines (An exception to this exists in the case of the emergency supply by pharmacists under strict conditions of benzylpenicillin, including procaine penicillin, in preparations for intramuscular use in animals). Reference to the label of a product will usually indicate the poisons schedule classification applicable to that product. For example, the label on an S4 drug is headed "PRESCRIPTION ONLY MEDICINE" or "PRESCRIPTION ANIMAL REMEDY" and on an S8 drug, "CONTROLLED DRUG", while S2 or S3 medicines are labelled "PHARMACY MEDICINE" or "PHARMACIST ONLY MEDICINE" respectively.

### Injectable Steroids: ("anabolic/androgenic steroids")

An Order under the Stock Medicines Act 1989 imposes controls on the supply, use, prescription and recording of these drugs additional to those applying under the Poisons and Therapeutic Goods Act. A summary of these controls is set out below, but any clarification necessary should be directed to the Department of Agriculture, Locked Bag 21, Orange NSW 2800 or tel (02) 6391 3722, fax (02) 6391 3740.

All injectable anabolic/androgenic steroids must be kept in a locked receptacle, eg cupboard, case, vehicle when not in immediate use.

- Veterinary surgeons are not permitted to supply injectable anabolic/androgenic steroids, except to another veterinary surgeon or to return them to the supplier. An exception exists for the supply of "sheep testosterone products". In this case, a veterinary surgeon may supply the product when they know the purchaser and know that the purchaser owns sheep which require treatment. The veterinary surgeon may supply sufficient product for a single course of treatment of the affected sheep.
- *A veterinary surgeon may not prescribe injectable anabolic/androgenic steroids.*

- Animals requiring treatment with an injectable anabolic/androgenic steroid must be injected by the veterinary surgeon personally or by a person acting under the direct personal supervision of the veterinary surgeon supplying the product.
- Records must be made and kept of all quantities received and used in detail similar to that required for drugs of addiction as set out further on in this Guide, the form of the records being at the veterinary surgeon's discretion, provided the records can be readily presented in a consolidated form when required. In the case of the supply of sheep testosterone products, the record must also include batch numbers of the products. Records must be made within 24 hours of the receipt or use of the product and kept for at least two years.
- Any loss or theft of more than 50mL of injectable anabolic/androgenic steroid during any 28 day period must be reported to the Department of Agriculture within 24 hours of discovery. **However, any loss or theft must be reported immediately to the Department of Health (tel 02 9879 3214) and, in the case of robbery, to the local police.**

### Prescriptions:

A veterinary surgeon may write a prescription for a restricted substance or a drug of addiction for veterinary treatment **only** and must endorse all such prescriptions with the words **“FOR ANIMAL TREATMENT ONLY”**.

A veterinary surgeon **must not** issue a prescription for or supply any poison, restricted substance or drug of addiction in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Each prescription is valid for 12 months from the date written, with the exception of prescriptions for those restricted substances specified in Appendix D to the Regulation (S4D) and drugs of addiction (S8), which are valid for 6 months only.

The prescription must bear the name, address and telephone number of the veterinary surgeon (may be pre-printed), and must include in ink in the veterinary surgeon's legible handwriting, unless otherwise approved (eg computer-generated in accordance with set criteria, a copy of which is available from the Pharmaceutical Services Branch - See “Further Information” on the last page of this Guide), the following particulars:

- (i) the date on which it was written;
- (ii) the name and address of the animal's owner, and the species of animal;
- (iii) the name, strength and quantity of the restricted substance or drug of addiction to be dispensed (in the case of a drug of addiction, the **quantity** must be written in both **words and figures**);
- (iv) adequate directions for use;
- (v) the number of repeats, if the prescription is to be dispensed more than once;
- (vi) in the case of a prescription for a drug of addiction, an anabolic/androgenic steroidal agent or amylobarbitone or pentobarbitone injection which is directed to be dispensed more than once, the **time interval** between repeat dispensings; and
- (vii) the signature of the veterinary surgeon.

All details other than (i) and (ii) on a computer-generated prescription for a **drug of addiction** must also be **handwritten** by the veterinary surgeon.

In the case of a drug of addiction, **no other item** may be written on the same form (including no other preparation containing a drug of addiction).

A veterinary surgeon **may not** issue a prescription for, nor supply, the following drugs of addiction -

amphetamine dexamphetamine methylamphetamine  
phendimetrazine phenmetrazine

A veterinary surgeon may not issue a prescription for the drug of addiction **methylphenidate** (Ritalin, Ritalin LA, Attenta) in either tablet or injectable form, although they may supply the tablet form directly to an animal owner for administration to the animal or they may personally administer it to the animal. (Such supply of the substance must be recorded in the treatment record for the animal and in the practice drugs of addiction register).

Where, in the case of an **emergency**, a veterinary surgeon either by telephone, electronic mail or facsimile, authorises a pharmacist to supply a restricted substance or drug of addiction, a prescription must be written forthwith and forwarded within 24 hours to the pharmacist in confirmation of the earlier instruction. (Note: A facsimile or electronic mail message still has to be followed up by a written prescription).

Prescriptions must be written as set out above. Under no circumstances are slips of paper bearing only the product name acceptable as prescriptions.

### Prescribing Records:

Each time a veterinary surgeon writes a prescription for (or supplies) an Appendix D drug (see below) or a drug of addiction they **must make a record**, e.g. on a treatment card, of:

- the date of the prescription or supply,
- the name and address of the animal's owner and the species of animal, the drug name, strength and quantity,
- the number of repeats (if any) and, in the case of an anabolic/androgenic steroidal agent, amylobarbitone or pentobarbitone injection and drugs of addiction, the repeat intervals, and
- the directions for use shown on the prescription or label.

Appendix D includes such Schedule 4 substances as :

anabolic and androgenic steroidal agents benzodiazepines  
such as diazepam ketamine

**Note:** The oral forms of the short acting barbiturates such as amylobarbitone and pentobarbitone which were in Appendix D are now in Schedule 8 as is flunitrazepam. Amylobarbitone and pentobarbitone injections remain in Schedule 4 (Appendix D) as do all forms of phenobarbitone and methylphenobarbitone.

A list of Appendix D substances (TG14) is available from Pharmaceutical Services Branch (see last page of this Guide).

**Note:** Unauthorised possession of an Appendix D drug is an offence. Furthermore, if any Appendix D drug is lost or stolen, the veterinary surgeon must immediately notify the Department of Health (tel (02) 9879 3214) and, in the case of robbery, the local police.

### Supply or Sale of Animal Medicines:

A veterinary surgeon may supply scheduled substances for use in the course of animal treatment **ONLY**.

A veterinary surgeon must not prescribe or supply any poison, restricted substance or drug of addiction in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

#### Labelling:

When a veterinary surgeon supplies a restricted substance (S4) or a drug of addiction (S8) to an animal owner, whether in the manufacturer's original pack or repacked into another container, the veterinary surgeon **must label** the primary container e.g. bottle or carton with the following details:

- the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background;
- the name of the animal's owner and the species of animal;
- adequate directions for use (should be explicit - people tend to forget verbal directions);
- the name and address of the veterinary surgeon;
- in respect of a preparation for external use the word "POISON" or the words "FOR EXTERNAL USE" in red on a white background; and
- the name of the preparation unless it is a preparation compounded in accordance with the veterinary surgeon's own formula.

#### Packaging:

In most cases, the preparation would be expected to be supplied in its original container. Where the veterinary surgeon wishes to supply a smaller quantity and has to repack it into another container, this **container** should

- be sufficiently strong to prevent leakage arising from the ordinary risks of handling, storage or transport; and
- be securely closed and be capable of being reclosed (other than a preparation packed for use on one occasion only).

Containers such as paper envelopes cannot meet these parameters and should not be used.

A poison or restricted substance in liquid form intended for external animal use should be supplied in a container which has the outer surface embossed with the words "POISON" or the words "NOT TO BE TAKEN" as well as, in the case of bottles, prominent vertical ribs or other such device as will render it distinguishable by touch from other containers ordinarily used for foods, internal medicines etc.

THE USE OF CLEAR GLASS UNMARKED MEDICINE BOTTLES FOR POISONOUS PREPARATIONS INTENDED FOR EXTERNAL USE IS HAZARDOUS AND UNLAWFUL.

Veterinary surgeons must keep in mind that once a product leaves the veterinary surgery, even though it may be intended for animal use, there is always the possibility of accidental human ingestion. Hence the need for appropriate packaging and labelling, including the use of child-resistant closures where indicated.

It should be noted that a restricted substance for animal use may be supplied or used only by the veterinary surgeon **personally** or by an assistant working under their **direct personal supervision**. A similar level of supervision should be applied to the supply of Schedule 2 or 3 preparations. It is illegal for an unregistered assistant to supply such an item in the absence of the veterinary surgeon, with or without their consent.

#### Records of Supply:

Note: Refer to the "DRUGS OF ADDICTION" Section regarding special requirements for drugs of addiction.

Every time a veterinary surgeon supplies a restricted substance in a quantity sufficient for **more than 3 days' treatment** they must make a record (eg. on a treatment card) of the supply, showing:

- the date on which it was supplied;
- the name, strength and quantity of the substance supplied; and
- the name and address of the animal's owner, and the species of animal.

This record must be retained at the surgery for two years and be made available for inspection if required.

#### Pesticides:

Pesticides are registered under the Pesticides Act 1999, but must also be packaged and labelled in accordance with the Poisons and Therapeutic Goods Regulation 2002. They may be classified in Schedule 5, 6 or 7 of the Poisons List (or be unclassified) and are subject to differing requirements depending upon the Schedule applicable to the product.

#### Schedule 5 and 6 Pesticides:

Substances in these schedules which are registered pesticides must be supplied in a container bearing a label which complies with the full labelling requirements of the Poisons and Therapeutic Goods Regulation and the Pesticides Act and which is registered as a pesticide. Veterinary surgeons may only recommend the use of a pesticide in accordance with the directions on the label and may not legally repackage or relabel a registered product. Contact the Environment Protection Authority for further detail.

#### Schedule 7 Pesticides:

Pesticides in this schedule are extremely toxic, having an acute oral LD50 ranging from 4 or 5mg/kg to 40 or 50mg/kg. They must be stored in a room or enclosure to which the public does not have access.

Apart from the supply of pesticides included in Schedule 7 **in the manufacturer's original pack** there would be very few instances where a veterinary surgeon could supply such a pesticide legally under the Poisons and Therapeutic Goods Act. In particular, it is an offence under this Act to repack and supply small bottles e.g., 50mL or 100mL of any Schedule 7 pesticide for **any** purpose, let alone any prohibition provided by pesticides legislation. It is clear that these substances are far too toxic for domestic use, the regulations being designed to deter such use while still making them available for commercial purposes. Aside from and of more importance than the legal aspects is the very real hazard to the repacker and the client or a child from such toxic chemicals.

Schedule 7 poisons include such substances as chlorfenvinphos, ethion and parathion.

#### Storage and Disposal of Poisons and Restricted Substances:

Substances specified in Schedule 3, 4 and 7 of the Poisons List are to be stored in a part of the premises to which the public does not have access, for example in a cupboard or drawer in the surgery or in a storeroom, **not** the waiting room.

Schedule 6 poisons, excluding those packed and labelled for internal use in animals, are required to be stored either

- in a place to which the public does not have access e.g., a storeroom, or
- at least 1.2m above the floor (out of the reach of young children).

This requirement does not apply to those preparations which are packed in containers of 5 litres (or 5 kilograms) or more, or to those preparations which are packed in containers with child-resistant closures.

It is an offence to dispose of any poison or restricted substance in any place or manner likely to constitute a risk to the public. Inquiries about safe disposal may be made to the Pharmaceutical Services Branch, N.S.W. Department of Health on (02) 9879 3214.

### Drugs of Addiction (Schedule 8 Drugs):

#### Procurement:

A veterinary surgeon must issue a signed order before they can be supplied with a drug of addiction. The signed order is cancelled and retained by the supplier. If a drug of addiction is ordered by telephone the signed order must be forwarded to the supplier within 24 hours.

#### Storage:

Drugs of addiction must be stored apart from all other goods in a separate room, safe, cupboard, or drawer which is securely fixed to the premises and kept locked when not in immediate use. The intention is that this room, safe, drawer or cupboard should be opened only to obtain drugs of addiction. The above requirements do not apply to emergency supplies kept in a bag in a room or vehicle which is locked when not occupied by the veterinary surgeon.

If a drug of addiction becomes unwanted or is out of date, it may be destroyed only under the supervision of a member of the police force or an authorised officer of the Department of Health (phone Pharmaceutical Services Branch on (02) 9879 3214).

If any drug of addiction is **lost or stolen**, the veterinary surgeon must immediately notify the Duty Pharmaceutical Adviser, Pharmaceutical Services Branch, on (02) 9879 3214 and, in the case of robbery, a police officer and enter the relevant details in the drug register.

#### Records:

A veterinary surgeon who uses or obtains any drug of addiction must keep a separate register in which are to be entered in ink the details of each receipt, supply or use. No alteration may be made in the register, but any mistake may be corrected by a marginal note or footnote, initialled and dated. The register must be kept on the premises on which the drugs of addiction are stored and must be retained for a period of two years from the date of the last entry and made available for inspection if required. Entries are to be made **on the day of receipt, supply or use**, a separate page being used for each kind of drug and each strength of drug. Details required to be entered in the drug register are:

- the date of the entry;
- the name and address of the supplier (in the case of receipt), or the name and address of the animal's owner and the species of animal (in the case of administration or supply);
- the quantity received, supplied or used and the balance held after the transaction;
- the name of the veterinary surgeon authorising the supply or use; and
- the signature of the actual supplier or user.  
*((iv) and (v) would, in most cases, be the same person)*

A "Register of Drugs of Addiction" can be purchased from most veterinary or pharmaceutical wholesalers or from the N.S.W. Government Printing Service, PO Box 256, Regents Park 2143, Phone (02) 9743 8777, Fax. (02) 9743 8603. Alternatively, an exercise book in which the pages are numbered consecutively and which has columns ruled as shown below, could be used. Each preparation of a drug of addiction and each strength must be on a separate page.

#### Drug name, Form And Strength .....

Date	Name & Address of Person Supplied or From Whom Received	Qty In	Qty Out	Balance	Name of Authority	Signature of Person Prescribing, Supplying or Administering

#### Stock Checks:

Twice a year, during March and September, veterinary surgeons must carry out a full stock check of all drugs of addiction in their possession. Immediately under the last entry for each drug they should write the date on which the check was made, the words "Balance on hand," the quantity actually held and should sign the entry. Any person who assumes control of a practice for one month or more should immediately perform a similar check irrespective of the time of year.

#### Out-Of-Date Stock:

It is illegal under the Poisons and Therapeutic Goods Act to supply any medicine, whether on prescription or over-the-counter, including those for veterinary use, after the expiry date shown on the label. There are no exceptions to this requirement, including giving them away or "specialling" them, even if the customer is advised beforehand that the goods have passed their expiry date.

#### Further Information:

The following brochures may be obtained from the Duty Pharmaceutical Adviser, Pharmaceutical Services Branch, NSW Department of Health, P.O. Box 103 Gladesville 1675. Phone: (02) 9879 3214. Fax: (02) 9859 5165 or at the Branch's website-[www.health.nsw.gov.au/public-health/psb/publications/pubs\\_list.html](http://www.health.nsw.gov.au/public-health/psb/publications/pubs_list.html)

List of Schedule 8 Drugs (drugs of addiction)	TG 13
List of Appendix D Drugs (Schedule 4 Appendix D)	TG 14
Criteria for issuing Non-Handwritten Prescriptions	TG184

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