

GUIDE TO POISONS AND THERAPEUTIC GOODS LEGISLATION FOR VETERINARY PRACTITIONERS

This Guide is a summary only and should be read in conjunction with the Poisons and Therapeutic Goods Act 1966 and the Poisons and Therapeutic Goods Regulation 2008 (obtainable from Fuji Xerox, Tel. (02) 9311 9899; also available on the Internet at www.legislation.nsw.gov.au) and the Poisons List (see below).

Further information may be obtained from the Duty Pharmaceutical Officer, Pharmaceutical Services, NSW Ministry of Health, Locked Mail Bag 961, North Sydney NSW 2059. Tel. (02) 9391 9944; Fax. (02) 9424 5860 or by email: pharmserv@doh.health.nsw.gov.au

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). The schedules align closely with those shown in the publication, "Standard for the Uniform Scheduling of Medicines and Poisons" (SUSMP), published by the Commonwealth under the Therapeutic Goods Act 1989 (available at: <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm#susmp> and obtainable from SUSMP Publication Officer, PO Box 7077, Canberra BC ACT 2610 Tel. (02) 6269 1035, Fax. (02) 6260 2770).

Following is a summary of the nature of the substances in each schedule. The requirements for the storage, supply, labelling, recording etc for Schedules 2, 3, 4 and 8 are detailed later in this Guide.

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 veterinary practitioners, medical practitioners, authorised nurse or midwife practitioners, pharmacists, dentists, authorised optometrists 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 practitioner would be likely to cause hardship.

Schedule 3 substances may be supplied only by veterinary practitioners, medical practitioners, authorised nurse or midwife practitioners, pharmacists, dentists or authorised optometrists. Where a pharmacist supplies such substances, they must be

personally handed to the patient by the pharmacist. Additional conditions may apply. Similarly, a veterinary practitioner 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 veterinary practitioner, medical practitioner, authorised nurse or midwife practitioner, dentist or authorised optometrist, or by a pharmacist on the written prescription of one of the aforementioned.

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 that should be readily available to the public for agricultural, pastoral, horticultural, veterinary, photographic or industrial purposes or for the destruction of pests.

Schedule 7

Substances of exceptional danger that 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.

SCHEDULE CLASSIFICATION

Preparations classified as restricted substances (Schedule 4) or drugs of addiction (Schedule 8) 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 a Schedule 4 drug is headed "PRESCRIPTION ONLY MEDICINE" or "PRESCRIPTION ANIMAL REMEDY" and on an S8 drug, "CONTROLLED DRUG", while Schedule 2 or Schedule 3 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. **For further clarification please contact the Department of Primary Industries, Locked Bag 21, Orange NSW 2800 or Tel. (02) 6391 3100; Fax. (02) 6391 3336.**

- All injectable anabolic-androgenic steroids must be kept in a securely locked receptacle, e.g. cupboard, case or vehicle when not in immediate use.
- Veterinary practitioners are not permitted to supply injectable anabolic-androgenic steroids, except to another veterinary practitioner or to return them to the supplier. An exception exists for the supply of “sheep testosterone products” under specified conditions.
- ***A veterinary practitioner cannot prescribe injectable anabolic-androgenic steroids.***
- For a veterinary practitioner to treat an animal with an injectable anabolic-androgenic steroid, the veterinary practitioner must either:
 - Personally inject the animal with the anabolic-androgenic steroid, or
 - Be in the immediate presence of the person injecting the animal with the anabolic-androgenic steroid.
- Veterinary practitioners must maintain a record of the injectable anabolic-androgenic steroids received, used and disposed of similar to that required for drugs of addiction as set out further on in this Guide. The records must be made within 24 hours of the receipt or use of the product and kept for at least two years.

Note: The loss or theft of more than 50mL of injectable anabolic-androgenic steroid during any 28 day period must be reported to the Department of Primary Industries within 24 hours of discovery. **However, the Poisons and Therapeutic Goods Regulation 2008 mandates that any loss or theft must be reported immediately to the NSW Ministry of Health (Pharmaceutical Services) by completing the online ‘Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)’ located on the Internet at:**

<http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx>

and, in the case of robbery, to the local police.

PRESCRIPTIONS

A veterinary practitioner may write a prescription for a restricted substance (Schedule 4) or a drug of addiction (Schedule 8) for veterinary treatment **only** and must endorse all such prescriptions with the words "**FOR ANIMAL TREATMENT ONLY**".

A veterinary practitioner **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.

Prescriptions are valid for 12 months from the date written, with the exception of prescriptions for those prescribed restricted substances (Schedule 4 Appendix D) and drugs of addiction (Schedule 8), which are each valid for 6 months only.

The prescription must bear the name, address and telephone number of the veterinary practitioner (this may be pre-printed), and must include in ink, in the veterinary practitioner's legible handwriting, the following particulars:

- (i) the date on which it is 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 or a special restricted substance (Schedule 4 Appendix B) for example amylobarbitone or pentobarbitone injection, which is directed to be dispensed more than once, the **time interval** between repeat dispensing; and
- (vii) the actual signature of the veterinary practitioner.

All details other than (i) and (ii) on a computer-generated prescription for a **drug of addiction** must also be **handwritten** by the veterinary practitioner. A copy of the criteria for non-handwritten (computer-generated) prescriptions is available from the Pharmaceutical Services Unit - See "Further Information" on the last page of this Guide.

In the case of a drug of addiction, a **separate prescription form** is required for **each** preparation containing 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 practitioner **may not** issue a prescription for, nor supply, the following drugs of addiction:

- amphetamine
- dexamphetamine
- lisdexamfetamine
- methylamphetamine
- phendimetrazine
- phenmetrazine

A veterinary practitioner may not issue a prescription for the drug of addiction **methylphenidate** (Concerta®, Ritalin®, Ritalin LA®); although a veterinary practitioner may supply methylphenidate in solid dosage form directly to a person for administration to the animal or they may personally administer it to the animal. Any such supply of the substance must be recorded in the treatment record for the animal and in the drugs of addiction register.

Where, in the case of an **emergency**, a veterinary practitioner 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).

Prescribing Records

Each time a veterinary practitioner writes a prescription for a prescribed restricted substance (Schedule 4 Appendix D) or a drug of addiction (Schedule 8) they **must make a record**, e.g. on a treatment card (see also “Records” in the section on “Drugs of Addiction”), kept at the surgery, of:

- the date of the prescription;
- 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 prescriptions for a special restricted substance (Schedule 4 Appendix B) and drugs of addiction (Schedule 8), the repeat intervals; and
- the directions for use shown on the prescription.

Note: Ketamine and oral forms of the short acting barbiturates such as amylobarbitone and pentobarbitone are now in Schedule 8, as are alprazolam and flunitrazepam. Amylobarbitone and pentobarbitone injections remain in Schedule 4 Appendix D as do all forms of phenobarbitone and methylphenobarbitone.

A list of prescribed restricted substances (Schedule 4 Appendix D) is available from Pharmaceutical Services (see last page of this Guide).

Note: Unauthorised possession of a prescribed restricted substance (Schedule 4 Appendix D) drug is an offence. Furthermore, if a prescribed restricted substance is lost or stolen, the veterinary practitioner must immediately notify Pharmaceutical Services by completing the online ‘Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)’ located on the Internet at:

<http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx>

and, in the case of robbery, the local police.

DRUGS OF ADDICTION (SCHEDULE 8)

Procurement

Unauthorised possession of a drug of addiction (Schedule 8) is an offence.

A veterinary practitioner 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 that 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 accessed only by the veterinary practitioner to obtain drugs of addiction.** The above requirements do not apply to emergency supplies kept in a bag in a room or vehicle that is locked when not occupied by the veterinary practitioner. A room or cupboard is not “locked” if the key is left in the lock or is otherwise readily accessible to anybody.

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 form and strength of drug. Details required to be entered in the drug register are:

- (i) the date of the entry;
- (ii) 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);
- (iii) the quantity received, supplied or used and the balance held after the transaction;
- (iv) the name of the veterinary practitioner authorising the supply or use; and
- (iv) the signature of the veterinary practitioner actually supplying, using or administering the drug.

Note: (iv) and (v) would normally be the same person.

Drug registers can be purchased from most veterinary and pharmaceutical wholesalers or from Fuji-Xerox Tel. (02) 9311 9899. Alternatively, a bound exercise book in which the pages are numbered consecutively and which has columns ruled as shown on the following page, could be used. Each preparation of a drug of addiction and each strength must be listed on a separate page.

It is an offence to make false or misleading entries in a drug register.

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

It is permissible to use the drug register to record the use of injectable anabolic steroids for the purposes of the Stock Medicines Act Order referred to on page 3 of the Guide.

Stock Checks

Twice a year, during March and September, veterinary practitioners 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.

Destruction

If a drug of addiction becomes unwanted or is out of date, it may be destroyed under the supervision of a police officer, by an authorised officer of the Ministry of Health (phone Pharmaceutical Services on (02) 9391 9944) or by a retail pharmacist in the presence of the veterinary practitioner either at the latter's premises or at the pharmacy. In all cases the destruction must be recorded in the practitioner's drug register, signed and dated by the person carrying out the destruction and co-signed by the practitioner. A pharmacist must also include their name and professional registration number in the entry.

Loss or theft of a drug of addiction

If a drug of addiction is **lost or stolen**, the veterinary practitioner must immediately notify Pharmaceutical Services by completing the online 'Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)' located on the Internet at:

<http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx>

and, in the case of robbery, a police officer and enter the relevant details in the drug register.

SUPPLY OR SALE OF ANIMAL MEDICINES

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

A veterinary practitioner 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.

Wholesalers may not supply a restricted substance (Schedule 4) or drug of addiction (Schedule 8) on veterinary order directly to an end-user. That is, a wholesaler cannot directly supply to the owner of an animal on the direction of a veterinary practitioner. Such substances may only be supplied by a wholesaler to a veterinary practitioner who must then supply the product to the user. Only pharmacists may supply to end-users on prescription.

Labelling

When a veterinary practitioner supplies a restricted substance (Schedule 4) or a drug of addiction (Schedule 8) to an animal owner, whether in the manufacturer's original pack or repacked into another container, the veterinary practitioner **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;
- if the substance is intended for external use only the word "POISON" or the words "FOR EXTERNAL USE ONLY" in red on a white background;
- the approved name, strength and quantity of the substance and its proprietary name, unless it is a preparation compounded extemporaneously in accordance with the veterinary practitioner's own formula;
- adequate directions for use, which should be explicit as people tend to forget verbal directions;
- the name of the animal's owner and the species of animal; and
- the name and address of the veterinary practitioner.

It is not necessary to repeat any details which are already included on the label of the dispensed product, such as the approved name and the product name, provided they are not obscured by the dispensing label.

All supplied containers must carry a label as described above, even if there are large numbers supplied and the labels are the same. It is not acceptable to label a carton with several unlabelled containers inside. The presence of the dispensing label on the container indicates that the product has been supplied by a veterinary practitioner.

Packaging

In most cases, the preparation would be expected to be supplied in its original container. Where the veterinary practitioner 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 practitioners need to keep in mind that once a product leaves the veterinary practice, 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 practitioner **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 (e.g. receptionist or veterinary nurse) to supply such an item in the absence of the veterinary practitioner, with or without their consent. However, an assistant may despatch these products by mail or courier to the user under direction of the veterinary practitioner.

Records of Supply

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

Whenever a veterinary practitioner supplies or sells a restricted substance, including a clinical sample, they must make a record (e.g. 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 by the Australian Pesticides and Veterinary Medicines Authority, but must also be packaged and labelled in accordance with the Poisons and Therapeutic Goods Regulation 2008. They may be classified in Schedule 5, 6 or 7 of

the Poisons List (or be unscheduled) and are subject to differing requirements depending upon the Schedule applicable to the product.

Schedule 5 and 6 Pesticides

Substances in these schedules that are registered pesticides must be supplied in a container bearing a label that complies with the full labelling requirements of the Poisons and Therapeutic Goods Regulation and that required as a condition of pesticide registration. Veterinary practitioners 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 NSW Environment Protection Authority (EPA) for further information (see <http://www.epa.nsw.gov.au/pesticides/index.htm>).

Schedule 7 Pesticides

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

Apart from the supply of a pesticide (within the meaning of the *Pesticides Act 1999*) included in Schedule 7 **in the manufacturer's original pack** there would be very few instances where a veterinary practitioner 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, as well as 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 or 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 that are packed in containers of 5 litres (or 5 kilograms) or more, or to those preparations which are packed in containers fitted with child-resistant closures.

NOTE: 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 Pharmaceutical Services, NSW Ministry of Health on (02) 9391 9944.

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 discounting them, even if the customer is advised beforehand that the goods have passed their expiry date.

FURTHER INFORMATION

Further information and copies of the latest versions of the following brochures may be obtained by contacting the Duty Pharmaceutical Officer during office hours on (02) 9391 9944 or visiting the Pharmaceutical Services website at:

<http://www.health.nsw.gov.au/pharmaceutical>

Title	Document No.
Drugs of Addiction (Schedule 8)	TG 13
Schedule 4 Appendix D Drugs (“Prescribed restricted substances”)	TG 14
Criteria for Issuing Non-Handwritten (Computer Generated) Prescriptions	TG 184

This guide has been produced by:

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