

**NSW HEALTH
PHARMACEUTICAL SERVICES BRANCH**

**GUIDE TO POISONS AND THERAPEUTIC GOODS LEGISLATION
FOR VETERINARY PRACTITIONERS**

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 2008 (obtainable from Salmat, Print on Demand, Phone 1300 656 986; 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 Adviser, Pharmaceutical Services Branch, NSW Department of Health, PO 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 that is uniform in most respects throughout Australia. Following is a summary of the nature of the substances in each schedule. The requirements for the storage, supply, labelling, recording etc for Schedules 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.

Other controls

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 Primary Industries, Locked Bag 21, Orange NSW 2800 or Phone (02) 6391 3722, Fax (02) 6391 3740.**

- All injectable anabolic/androgenic steroids must be kept in a locked receptacle, e.g. cupboard, case, 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 may not prescribe injectable anabolic/androgenic steroids.***
- Animals requiring treatment with an injectable anabolic/androgenic steroid must be injected by the veterinary practitioner personally or by a person acting under the direct personal supervision of the veterinary practitioner 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. 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 Primary Industries within 24 hours of discovery. **However, any loss or theft must be reported forthwith to the Department of Health (Phone 02 9879 3214) and, in the case of robbery, to the local police.**

PRESCRIPTIONS

A veterinary practitioner 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 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 restricted substances specified in Appendix D to the Regulation (S4D) and drugs of addiction (S8), 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 amylobarbitone or pentobarbitone injection which is directed to be dispensed more than once, the **time interval** between repeat dispensings; 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 Branch - See "Further Information" on the last page of this Guide.

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

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

amphetamine
dexamphetamine
methamphetamine
phendimetrazine
phenmetrazine

A veterinary practitioner may not issue a prescription for the drug of addiction **methylphenidate** (Attenta, Concerta, Ritalin, Ritalin LA) 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. 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. Be aware that 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 practitioner writes a prescription for an Appendix D drug (see below) or a drug of addiction 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 amylobarbitone or pentobarbitone injection and drugs of addiction, the repeat intervals, and
- the directions for use shown on the prescription.

Appendix D includes such Schedule 4 substances as:

amylobarbitone and pentobarbitone injections
anabolic/androgenic steroidal agents (may not prescribe injectable forms)
benzodiazepines such as diazepam
ephedrine

Note: Ketamine and the oral forms of the short acting barbiturates such as amylobarbitone and pentobarbitone that used to be 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 practitioner must immediately notify the Duty Pharmaceutical Adviser, Pharmaceutical Services Branch, (Phone (02) 9879 3214) and, in the case of robbery, the local police.

DRUGS OF ADDICTION (SCHEDULE 8 DRUGS)

Procurement

Unauthorised possession of a drug of addiction (controlled drug) 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 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 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
- (v) the signature of the veterinary practitioner actually supplying, using or administering the drug.

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

A "Register of Drugs of Addiction" can be purchased from most veterinary or pharmaceutical wholesalers or from Salmat, Print on Demand (Phone 1300 656 986). Alternatively, a bound exercise book in which the pages are numbered consecutively and which has columns ruled as shown below, could be used. Each kind of a drug of addiction and each form and strength of drug must be 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 S8 drug register to record the use of injectable anabolic steroids for the purposes of the Stock Medicines Act Order referred to on page 3 .

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 member of the police force; by an authorised officer of the Department of Health (phone Pharmaceutical Services Branch on (02) 9879 3214); 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.

If any drug of addiction is **lost or stolen**, the veterinary practitioner 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.

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.

A veterinary wholesaler may not supply a restricted substance or controlled drug on veterinary order directly to an end-user. 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 (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 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;
- in respect of a preparation for external use 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 also, 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 such a label, 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 unclassified) 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 Chemicals Policy Section of the NSW Department of Environment and Climate Change (previously the EPA) for further information (see <http://www.environment.nsw.gov.au/pesticides/>).

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 pesticides 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, 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 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 the Pharmaceutical Services Branch, N.S.W. Department of Health on (02) 9879 3214.

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, and many others including this document, 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/PublicHealth/Pharmaceutical/resources.asp

List of Schedule 8 Drugs (drugs of addiction)	TG13
List of Appendix D Drugs (Schedule 4 Appendix D)	TG14
Criteria for issuing Non-Handwritten Prescriptions	TG184