

Guide for the Dispensing and Supply of Drugs and Poisons by Veterinary Surgeons Pharmaceutical Services Branch- March 2002

Summary:

The requirements for labelling and packaging of drugs and poisons relate to the Schedule of a substance.

1. Dispensing

Veterinary Surgeons must dispense Schedule 4 (more than 3 days supply) and Schedule 8 medicines with the labelling required under Regulation 56. Containers for some drugs are specified (Reg.84), otherwise a veterinarian should apply their professional judgement recognising the poisoning risk of medicines. A veterinary surgeon may choose to dispense Schedule 2, Schedule 3, Schedule 4 (up to 3 days supply), Schedule 5 and Schedule 6 drugs and poisons with the specified label (Regulation 87).

2. Supply of an original pack

A veterinary surgeon may supply Schedule 2, Schedule 3, Schedule 4 (up to 3 days supply), Schedule 5 and Schedule 6 drugs without a dispensing label. Supply should be in a manufacturer's original pack. Pharmaceutical Services Branch recommends against the repackaging of drugs and poisons.

3. Repackaging (Where a substance is not dispensed)

Repackaging of drugs and poisons is not recommended. If repacking of scheduled drugs and poisons is undertaken all information on the original pack should be supplied on any subsequent pack produced and the name of the practitioner and surgery included. Containers should be consistent with that of the original container.

Introduction

The requirements for labelling and containers for drugs and poisons included in the Tasmanian Poisons List relate to the schedule(s) in which the drug or poison appears. A general description of the schedules is attached (Appendix 1).

1. Schedule 4 (Prescription Only Medicine or Prescription Animal Remedy) and Schedule 8 (Controlled Drug)

1.1. Schedule 4 Dispensing

Regulation 43 of the Tasmanian Poisons Regulations 2002 states that:

?? a veterinary surgeon may only sell or supply a Schedule 4 (S4) substance for use in the course of animal treatment (sale or supply to another veterinary surgeon is also permitted).

- ?? Where a quantity exceeding that required for 3 days treatment is sold or supplied a veterinary surgeon shall comply with the following conditions:
- (a) before the S4 is sold or supplied a record is to be made showing:
 - (i) date on which it was supplied
 - (ii) the name and address of the owner of the animal
 - (iii) the name of the substance and the quantity supplied
 - (b) the container bears the particulars prescribed in Regulation 87 (Dispensed medicines- see below)
 - (c) the record of the supply is kept at the surgery or office of the person by whom that substance was supplied or sold, and is produced on demand to an inspector.

Where the 3 day exemption provision is invoked a veterinary surgeon should ensure that sufficient written directions are provided for a client to safely use a medicine and that labelling and packaging are appropriate and do not pose a public health risk. Ideally in this instance any supply without a dispensing label should be in a manufacturer's original pack; alternatively, information from a manufacturer's original pack should be included when repacking is undertaken.

1.2. Schedule 8 (Narcotic drug) Dispensing

- ?? No veterinary surgeon shall supply a narcotic substance to a person except for the purpose of its administration to an animal (Regulation 11). Sale or supply to another veterinary surgeon is permitted.
- ?? Please note that the 3 day exemption provision for S4 substances (Regulation 43) does not apply for Schedule 8 drugs and all supplies of this type for animal treatment must be dispensed and recorded.
- ?? A veterinary surgeon must record any S8 transactions in an approved narcotic register or day book*.
- ?? All particulars of a supply (name, address, date, particulars of drug, directions and any repeats)are to be recorded. (Regulation 16)
- ?? Dispensing of narcotic substances
Where a narcotic prescription is dispensed by a veterinary surgeon he or she shall mark in ink on the container a reference to an entry in the narcotic substances register or day book*.(Regulation 22)

* A day book is defined as any continuous written record indicating the medicines or narcotic substances supplied to patients.

1.3 Labelling of Dispensed Medicines-Schedules 2, 3, 4 or 8 (Regulation 87)

This regulation states that when a scheduled substance is dispensed by a veterinary surgeon for the purposes of animal treatment the requirements of other provisions of the regulations relating to labels are waived if the container is labelled with the following:

- (a) "Keep out of reach of children" in red on a white background
- (b) The name of the owner of the animal
- (c) The name and address of the seller
- (d) Where the substance is for external use it is labelled with "Poison" or "Caution- not to be taken" or Do not swallow"
- (e) Where a drug may cause birth defects a specified warning is attached (refer to Appendix 2)
- (f) The words " For animal treatment only"
- (g) Adequate directions for its use in the treatment of the animal for whose treatment it was supplied
- (h) The name and strength of the scheduled substance

Note that any number or letter is to be at least 1.5mm high and in clear and distinct contrast to the background.

A veterinary surgeon may choose to either dispense a Schedule 2 or 3 substance or supply it in a manufacturer's original pack.

1.4. Containers for dispensed medicines

Regulation 84 (Child-resistant packaging of certain medicines) specifies that the following substances must be provided in child-resistant containers:

- Solid dosage forms- antiarrhythmics, anticonvulsants, antihistamines, aspirin, , chloroquine, digitalis glycosides, diphenoxylate hydrochloride with atropine sulphate, fluoride salts (in packs containing >100mg fluoride), glutethimide, iron compounds (doses >5mg), lithium carbonate, monoamine oxidase inhibitors, orphenadrine, paracetamol, quinine, salicylamide, tricyclic antidepressants
- Liquid preparations- digitalis glycosides, eucalyptus oil (>50% and 200ml or less), iron (contents >250mg), melaleuca oil (>25% cineole and 200ml or less), methyl salicylate (>50% and 200ml or less), paracetamol (except packs <2g).

Most blister and foil packaging will qualify as child resistant.

Otherwise containers are not specified by the Poisons Regulations for drugs and poisons for the following uses:

- (a) animal internal use; or
- (b) as a solid or semi-solid preparation for animal external use.

Similarly, other than for Regulation 84, containers for dispensed medicines are not specified.

The provision of appropriate containers(other than for substances subject to child-resistant closure requirements) is a matter for professional judgement. When deciding about containers veterinary surgeons should be cognisant of public health considerations. Inappropriately packaged drugs and poisons may pose a poisoning risk, particularly to young children.

Where possible drugs and poisons should be provided in a manufacturers original pack. Manufacturer's packaging will have been approved by either the National Registration Authority (N.R.A.) or the Therapeutic Goods Administration (T.G.A.) and will be required to meet the applicable standards.

A veterinarian may choose to subdivide packs. Ideally in this instance solid oral dosage forms should be supplied in blister or foil packaging with a further outer package to which a label is attached. Most blister or foil packaging will be rated as child resistant. It is recommended that loose solid dosage forms be provided in a bottle with consideration given to addition of a child resistant closure for toxic substances and where a substantial quantity of drug is provided (Note requirements of Regulation 84). Child resistant packaging is available from the pharmaceutical wholesalers and specialist packaging suppliers.

Veterinary surgeons will also be familiar with the requirements to optimise storage conditions i.e. protection from light and moisture. Again these requirements are met by the provision of blister packaging or a securely closed opaque bottle.

2. Repackaging of Schedule 2, 3, 5 and 6 Substances (where dispensing is not undertaken)

In contrast to the dispensing process the repackaging of drugs and poisons is a more complex undertaking due to the requirement to meet both State and Commonwealth legislative specifications. The supply of manufacturers original packs is recommended wherever practicable as:

- Product labelling and packaging is reviewed by the National Registration Authority at registration of a product to ensure all applicable standards are met
- first aid, safety directions and warning statements are complete

2.1 Labelling

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) contains the legal requirements for the labelling of drugs and poisons that are for sale to the public. A booklet titled "A guide to labelling drugs and poisons in accordance with the standard for the uniform scheduling of drugs and poisons" is available. This guide will assist in labelling in compliance with the Tasmanian Poisons Act. Other references may need to be consulted including:

- ?? Vet Labelling Code: Code of Practice for Labelling Veterinary Chemical Products
- ?? Therapeutic Goods Order 48- General Requirements for Labels for Drug products
- ?? FAISD Handbook (Handbook of first aid instructions, safety directions and warning state)

2.2. Containers

The SUSDP contains specifications for containers. However an exemption does apply for animal internal use or for solid or semi-solid preparations for animal external use. Packaging is assessed by the NRA against their standard.

Appendix 2.

Regulation 87- Labelling of dispensed medicines (teratogenic, embryotoxic and embryofatal drugs)

In summary the amendment states that where the following medicines are dispensed the following warnings must appear on each pack:

Drug	Warning
Levocabastine	Do not use if pregnant
Acitretin Adapalene Etretinate Isotretinoin Thalidomide Tretinoin	Please note: All warnings apply to all agents in the left column For oral use WARNING- Causes Birth Defects Do not use if pregnant. Do not become pregnant during use or within (<i>Insert number of months as per approved product information</i>) month(s) of stopping treatment. For topical use Do not use if pregnant. WARNING- May cause Birth Defects.
Leflunomide	WARNING- Causes Birth Defects Do not use if pregnant (<i>Insert brand name</i>) remains in the body for many months after treatment has stopped. Do not become pregnant or father a child before consulting your doctor.
Misoprostol	CAUTION- (Name of substance) should not be used by pregnant women.

These warnings normally appear on manufacturer's original packaging. When dispensing please ensure that they are not obscured.