

Supply by veterinarians of repackaged drenches for large animals such as cattle, sheep, goats, alpaca etc.

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Background

Only products registered for use in food producing species can be used to treat food producing species in most jurisdictions. Treatment of species not on the label may, in most cases, only be done by owners if they have written directions from a veterinarian which include a withholding period sufficient to ensure no residues are present at the time the animal is killed or milk collected.

Drench products (anthelmintics or worm treatments) are usually packaged in large volumes which may be unsuitable for those with small holdings, or have only limited use on larger properties (e.g. as part of quarantine treatments or as part of worm egg count reduction tests (DrenchTests)).

Dispensing smaller volumes to clients is quite legal provided certain requirements are met by the supplying veterinarian.

The primary concern is that these products must not be supplied in ways which impinge on their registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Since they are to be dispensed to clients they should not be displayed for sale. Display implies the products are registered for open sale, which is not the case. Signage at the premises could indicate that small volumes of drenches for sheep, cattle, goats, alpaca etc. are available to clients. Horse products are already available in such forms.

The APVMA approves products at three levels – the chemical in the container, the label on the container, and the container itself.

Selling a product over the counter without all three levels of approval is illegal supply under the Commonwealth Agricultural and Veterinary Chemicals Code Act 1994.

So, simply repacking into smaller containers which are not approved containers for the product is not permitted, even if the product is registered and a copy of the approved label is supplied. However, dispensing laws allow a registered veterinarian to supply smaller quantities to bona fide clients provided they comply with the following further requirements.

What can be done

The NSW Poisons and Therapeutic Goods Regulation 2008, clause 7(2), allows for supply of poisons (virtually all of the sheep/cattle drenches are S5 or S6 poisons) by a registered veterinarian in an alternative package provided it is labelled in accordance with the requirements of Appendix A of that Regulation. Appendix A gives the wording to be included on a dispensing label when a veterinarian supplies any repacked product (such as used on commonly dispensed antibiotics, anti-inflammatories or worm medications for small animals).

(For more information on the Poisons requirements see the NSW Health website article at http://www.health.nsw.gov.au/resources/publichealth/pharmaceutical/pdf/poisons_veterinary.pdf.)

The preamble to Appendix A, supported by verbal advice from NSW Health, indicates that the dispensing label only needs to include information

which is not on the existing label of the dispensed product.

So, if a veterinarian provides a copy of the product label (which should be attached to the container) when they dispense the product then all the directions for use, including dosing by weight, species and withholding period, are already provided and do not need to be duplicated on the dispensing label, which must be attached to the container.

As a result only the following would be required on the dispensing label in addition to the copy of the product label:

- The name and address of the supplier = the veterinary practice.
- KEEP OUT OF REACH OF CHILDREN in red on white = required on dispensing labels now.
- The name of the animal's owner = the owner you are supplying.

A reference on the dispensing label to the attached label directions for use is highly desirable in case the copy of the product label is detached or lost.

While the Regulation does not stipulate suitable containers, since most if not all drenches are packed in HDPE. Such containers should also be used for dispensed products.

Part 6 of the Regulation specifies requirements for the repackaging process at (veterinary) premises. These cover contamination, personal cleanliness, restrictions on smoking etc, contact with the product, wearing of bandages, infectious diseases and use of equipment. The Regulation, with Appendix A and all relevant details, is available at:

<http://www.legislation.nsw.gov.au/maintop/view/infoce/subordleg+392+2008+cd+0+N>.

Clients will also need to be provided with equipment to give the drench to their animal/s. For oral drenches this may be a syringe, but using this rather than a drench gun may require greater care to ensure the animal gets the whole dose. Loaded syringes could be provided for injectable drenches, but the veterinarian must ensure the client can use them correctly and safely.

Dispensing pour-on products is not recommended. A special applicator is usually required to apply a long stripe to the back of the animal and this cannot be done correctly without the right equipment. In addition they contain solvents which may affect repacking containers or those handling them.

In NSW insecticidal dips and sprays, which require dilution prior to use, are not permitted to be decanted and should not be repacked. These are

regulated by different legislation in NSW, the Pesticides Act 1999. From a safety perspective veterinarians would be unwise to repack and dispense such products even in jurisdictions where it might be legal.

Summary

- Veterinarians cannot display or market re-packed drenches over the counter since the containers are not approved containers.
- Veterinarians can dispense drenches to clients.
- Signage could be used to indicate that such products are available to clients.
- Veterinarians must only dispense to bona fide clients, since a name is required on the label. The practice records should indicate the sale to the client.
- If original product label copies are provided attached to the dispensed product, only minimal information is required on the dispensing label, as indicated above. Alternatively all Appendix A details must be provided. This alternative is not recommended since no first aid and safety directions would be included.
- Containers which are of the same type of material as the original product should be used.
- Relevant standards for repacking under the Regulation must be observed.
- Appropriate application equipment is required.
- Pour-on drenches should not be dispensed.
- Pesticides requiring dilution should not be dispensed.

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