

Agvet Chemicals Task Group – Veterinary Prescribing and Compounding Rights Working Group

Submission from the Australian Veterinary Association Ltd



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About us

The Australian Veterinary Association is the national organisation representing veterinarians in Australia. Our 8500 members come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, farm animals, such as cattle and sheep, and wildlife. Government veterinarians work with our animal health, public health and quarantine systems while other members work in industry for pharmaceutical and other commercial enterprises. We have members who work in research and teaching in a range of scientific disciplines. Veterinary students are also members of the Association.

Introduction

Thank you for the opportunity to provide advice to the Agvet Chemicals Task Group (ACTG) in relation to the discussion paper generated by the Veterinary Prescribing and Compounding Rights Working Group (VPCR WG).

The AVA strongly supports the COAG principle of national harmonisation of regulation of veterinary prescribing and compounding, and notes that this was also a recommendation of the recent 2016 draft report by the Productivity Commission on *Regulation of Australian Agriculture*.

We support the working group's stated aim to increase the level of harmonisation, rather than undertake a major review of the first principles of veterinary prescribing and compounding rights. Harmonisation of control-of-use legislation across jurisdictions will reduce confusion and create efficiencies in Agvet chemical use within Australia. It will help to ensure responsible use which safeguards trade, the environment, and human health, while ensuring a high level of protection of animal health and welfare.

We understand that at this stage, only high level comments are sought on the specific items identified in the working group's initial discussion paper. The AVA looks forward to providing comprehensive input on the details of the proposals, as further opportunities for consultation and engagement develop.

Off-label use and compounding

The AVA strongly supports development of a nationally harmonised system that allows veterinarians to continue to exercise their professional judgement to treat animals in their care. As such we support the intent of the nationally endorsed regulatory model which allows veterinarians to:

- (a) compound and supply veterinary chemical products under certain conditions,
- (b) prescribe off-label uses for prescription and non-prescription products, and
- (c) use or prescribe unregistered products for food producing species in certain circumstances.

Veterinarians are highly trained medical professionals and have the required knowledge to undertake these practices while ensuring any risks to human health, trade or the environment are appropriately managed. The veterinarian's prerogative to exercise clinical judgement in these circumstances is essential for the ongoing protection of animal health and welfare.

However, it is acknowledged that off-label use in food-producing and trade species raises concerns about residues that may jeopardise trade. Currently there is reasonable consistency across jurisdictions in rules which seek to ensure this does not occur (such as requirements for appropriate veterinary advice, labelling, record keeping and notifications of withholding periods) as outlined in the discussion paper. The AVA supports continuation of these safeguards and further harmonisation in terminology to ensure consistent implementation across jurisdictions.

In the absence of veterinary direction:

The AVA supports a continuation of the restrictions which must be followed in the absence of veterinary direction (items a – g, page 2 of discussion paper). It is our position that veterinary direction should be sought before treatment of an animal is proposed which will vary from the approved label use. The veterinarian is uniquely qualified to judge whether such variation will result in adverse outcomes for the animal, and also potentially other implications for trade or public health.

If administered or prescribed by a veterinarian:

Some changes to these restrictions are recommended, and covered below under the headings:

- Single animal treatments
- Treatment of related species

Animals under the veterinarian's direct care

A better definition of "animals under the veterinarian's direct care" is needed. This includes not only consideration of what constitutes "direct care", but also the timing of veterinary examinations, and intervals between these, that are permissible for the supply of prescription products.

The AVA position is that the supply of prescription animal remedies must be via a bone-fide vet-client-patient relationship, and that the vet must have seen the animal(s) sufficiently frequently to have good knowledge of the animal(s), the herd and any conditions being treated. As follows:

Before veterinarians can supply prescription animal remedies, they must be practising their profession. To do this, the veterinarian must meet the following criteria:

- The animals / herd must be under the care and supervision of the veterinarian; this care and supervision should be real and not merely nominal.
- The treatment recommended and the drugs supplied must be recorded.
- The client must be appropriately advised through written directions on the correct usage of the drugs.

When given responsibility for the health of the animal or herd in question by the agent or owner, the veterinarian demonstrates care and supervision by at least either:

- having seen the animal or herd for the purpose of diagnosis or prescription immediately before supply, or
- having visited the farm or other premises on which the animal or herd is kept, sufficiently often and recently enough to have acquired from personal knowledge and inspection an accurate picture of the current health state of the farm or premises; this must be sufficient to enable him or her to diagnose or prescribe for the animal or herd in question.

This allows for professional judgement and discretion, however can lead to uncertainty; hence harmonisation of acceptable timeframes as part of this review process would be supported, provided consideration of the issues faced in remote rural areas is taken into account. The AVA will be pleased to provide further advice on this issue as the consultation process develops.

Record Keeping

All practicing veterinary surgeons are legally and professionally obligated to ensure they maintain appropriate clinical records. This applies to all professional services and includes details of all medications administered, prescribed or dispensed. The various veterinary surgeons Acts within the jurisdictions dictate how long these records must be kept legally, and there is some variation in this between jurisdictions which may benefit from harmonisation.

Further information is available in the AVA policy *Retention of medical records and diagnostic images*:

<http://www.ava.com.au/policy/173-retention-medical-records-and-diagnostic-images>

Single Animal Treatments

Where it is permitted to use a veterinary chemical contrary to a label restraint for a single animal, it is appropriate that this be extended to include other in-contact animals or animals within that group. This is consistent with the principles of good disease management and control practices, as well as good animal welfare. It is our understanding that South Australia has adopted this approach, and we would recommend that any harmonisation seek to reproduce that approach nationally.

Veterinarians have the professional knowledge to not only determine when it is appropriate to extend use from the single animal to in-contact animals, but also to manage any associated risks.

Treatment of Related Species

“Do not use” statements and label restraints can be problematic, particularly with regards treating related species. It can mean an inability to treat animals in certain circumstances, leading to poor animal health and welfare outcomes, even in situations where there may be no actual benefit in terms of risk mitigation.

For example many medicines, drenches and anti-parasitics developed for sheep are labelled “do not use” for goats and alpacas by default if there is no specific withholding period data available for those species. Also some products are labelled “do not use” by default if the animal may at some time in their life be used to produce milk.

Often there is negligible likelihood of residues, based on usage and residue patterns of the same active formulation used in equivalent species, but the “do not use” restriction makes such use illegal. This precautionary approach limits the potential for these animals to be treated. A default withholding period similar to that used in New Zealand would be a better approach, for example a 35 day default withholding period used for milk from treated animals for certain veterinary chemicals.

It is our position that veterinarians should be able to use their discretion to use these medicines in variance with label restraints, based on their clinical judgement, and cross-species knowledge.

Veterinary direction should always be sought before treatment of an animal is proposed which will vary from the approved label use.

Minor Trade Species versus Minor Food Species

The AVA supports a harmonisation of terminology across jurisdictions on this issue.

Use of Compounded Products

The AVA has developed guidelines for the use of compounded products:

http://www.ava.com.au/sites/default/files/AVA_website/News/Guidelines-for-preparation-and-use-of-compounded-pharmaceuticals.pdf

All species deserve the benefit of medicinal products that are most suitable for their particular needs. Veterinary practitioners must be able to use their clinical judgement to prescribe a compounded medicine where no suitable registered veterinary product is available. “Suitability” may include consideration of whether a more appropriate dosage form, flavouring or method of administration is needed to suit the individual animal’s needs. In other words, if there is a clinical advantage to choosing the compounded product over the registered veterinary product, the use is justified on the basis of ensuring the animal’s welfare.

The AVA guidelines include a decision flow chart (page 2) which represents best-practice decision making around use of either (i) a product registered for another species or (ii) a compounded product, in place of a registered veterinary product. The AVA supports use of this as a guideline rather than a compulsory “cascade” of this nature. This is because the veterinarian must be able to ensure the best outcomes for the individual patient. A compulsory requirement to use a registered veterinary product if one exists, whether or not another product may be more suitable, would result in many situations where animals could not be treated, and very poor animal welfare outcomes.

We would like to draw your attention to the Frequently Asked Questions section of the AVA Guidelines which

address issues around quantities of compounded products that can be prescribed or supplied (Questions 5 and 7). There are quite a few inconsistencies between jurisdictions on this issue, particularly where it is proposed to treat food producing species or more than one animal. The AVA recommends harmonisation of these requirements across jurisdictions be addressed as part of the current review.

We look forward to providing further comment as additional details of the review are released.

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