Consultation Draft of Proposed draft regulations to replace the Drugs, Poisons and Controlled Substances Regulations 2006

Submission from the Australian Veterinary Association Ltd (Victorian Division)

www.ava.com.au

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The Australian Veterinary Association (AVA) 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.

The Australian Veterinary Association (Victorian Division), in general, support the proposed changes. Most feedback and comments relate to instances where we believe that the proposed regulations will not achieve their intended outcome.

For example, the regulations are amended to clarify the required content of dispensing labels on scheduled poisons and prescriptions, but the requirement for veterinary prescriptions/labels is that the "name **or** species" is required. We believe this is inadequate – the name could be "Jamie" and the species could be anything. The wording in current use (at http://agriculture.vic.gov.au/agriculture/farm-management/chemical-use/veterinary-chemicals/veterinary-practitioner-requirements) is superior. We will provide specific instances below, but as a general rule we believe the requirement should be "the species **and** identity of the animal(s) to be treated".

The second and major point we would like to make is that the current and proposed regulations provide very clear guidance on the supply and use of scheduled poisons by ***authorised*** persons but they do not adequately address the use of scheduled poisons supplied by ***unauthorised*** persons.

A significant emerging problem in agriculture is the supply and use of scheduled poisons by unauthorised persons. As examples, farmers are obtaining scheduled poisons (antibiotics and hormones) from the internet and from unregistered people (often artificial breeding businesses) who are openly illegally selling these products. This represents a risk to trade from residues, a risk to OHS from improper use, and dramatically increases the risk of antibiotic resistance. There has been a recent instance where a complaint was made by a farm worker that the farmer had illegally obtained schedule 4 poisons and intended to use these hormones on cattle. Whilst it is illegal to possess an S4 without appropriate authorisation, we understand that DHHS compliance officers only have power in relation to investigating authorised persons under the DPCS Act, which renders the act unenforceable and we were advised that the complaint could not be investigated except by police. There are several places in the proposed regulations where authorised people are prohibited from doing various things. The regulations do not recognise that these activities may be undertaken by unauthorised people as well, which is of utmost concern to the whole community. It is our view that these regulations should apply to **all** people – not just to those authorised.

Lastly, one of the aims of the amendments described in the commentary is to allow for plural – animal or animal(s). There are instances where the wording still needs some work. For example, prescriptions may be written for a litter of puppies, but the wording describes only herds or flocks; and there are several places where there are requirements for prescriptions written for "a specific animal" which would seem not to apply where prescriptions were written for multiple animals and it seems unlikely that this is the intent of the amendment.

Comments on new regulation

A new regulation has been proposed to assist in controlling and tracking supplies of medicated stock food. Provided below are comments on the proposed regulation and a proposed amended draft:

"Medicated Feed Order" is a term already in common use to describe this form of prescription (to a miller for stock feed rather than a pharmacist).

1. Legible and durable – we are unsure about durable (if a scanned electronic version is ok…)
2. The species of animals – this should in our view read "the species and class of animals, preferably including the average body weight"

3. The date on which the order was written – the timing issue is somewhat vexed. A date that the script was written is important, but this may not be the date that the script comes into effect (one may write one a week in advance for example)
4. The signature of the veterinarian – can it be an electronic signature? (presumably a fax/scanned copy is ok?)
5. Section g is problematic. Veterinarians should be prescribing the dose that the animal receives, and providing general mixing instructions. The brand is in our view is unimportant (ie. a generic brand should it exist…)
6. We suggest that the treatment purpose should be added as a requirement (ie. "Prevention of acidosis"); also a statement that therapeutic need must be established before writing a medicated feed order (which aids compliance, transparency about use and prevents retrospective scripts)
7. There should be a penalty for a miller for not following a medicated feed order (or making something not in compliance)
8. Farmers and Millers should have to produce prescriptions to authorised officers on request as well
9. The directions for use doesn't state that this advice must go with the feed to the farmer (and be followed!)
10. The duration of the script (ie. when the feed miller is allowed to supply feed) is different from the duration of treatment which is part of the directions for use (ie. animals must not be treated for more than xx days)
11. Veterinarians should not be the only ones in this chain capable of an offence. Millers and end users should also retain copies of medicated feed orders.

A first draft of a suggested version

(1) A veterinary practitioner who issues a medicated feed order for a manufacturer to supply a stock food containing a Schedule 4 poison must establish therapeutic need for the medication and ensure that the order is in writing and is legible and includes:

a. the name, registration number, address and telephone number of the registered veterinary practitioner issuing the order; and
b. the name and address of the owner or the person having the custody of the animals; and if different, the consignment address;
c. the species, type and weight of the animals; and
d. the date on which the order was written; and
e. the date on which the order comes into effect; and [the order might be written in advance]
f. the signature of the veterinary practitioner issuing the order; and
g. the name and address of the stock food manufacturer; and
h. particulars of the Schedule 4 poison to be supplied including:
    i. The type of feed
    ii. The active ingredient
    iii. The per animal dose of the Active Ingredient
i. Mixing instructions for the Miller that provide sufficient information for the Miller to determine the inclusion rate of the Schedule 4 poison in the ration; and
j. directions for use to be provided with the medicated feed, including the stock to be treated, the purpose of treatment, mandatory withholding periods, duration of treatment and any precautions or restraints; and
k. Duration of prescription (max 3 months)
xx penalty units

(2) A veterinary practitioner who issues a written order pursuant to subregulation (1) must keep a copy of the record of the order for a period of three years and produce it on demand to an authorised officer. xx penalty units

(3) A feed miller must keep a copy of the record of the order for a period of three years and produce it on demand to an authorised officer. xx penalty units

(4) A feed miller must comply with the directions on a medicated feed order xx penalty units

(5) An end user must comply with the directions for use xx penalty units

Other specific feedback

authorised prescriber *means a registered health practitioner authorised under section 13(1) of the Drugs Poisons and Controlled Substances Act 1981, who is authorised to prescribe within the lawful practice of the registered health practitioner's profession and where applicable, authorisation is noted on the registered health practitioner's endorsement of registration*.

Should this read "registered practitioner authorised under section 13(1)" rather than "registered health practitioner"? Later on, it clearly is intended to include veterinarians. As currently written it could be seen as only including the health practitioners described in 13(1) rather than all practitioners listed there.

Form (of stock food) includes pellets, mash;

The form of stock food should probably include grain: form (of stock food) includes grain, pellets, mash;

Prescription means a written instruction issued by an authorised prescriber to authorise a pharmacist in a pharmacy to supply the specified substances for the treatment of the person or animal named on the document.

Should there also be a definition for Medicated Feed Order (an instruction written by a registered veterinary practitioner to authorise a feed mill to mix and supply the specified substances for the treatment of the animals described in the document)?

The terminology for such an order used by Dairy Australia, AVA and AVMA is "Medicated Feed Order". It is recommended that this be adopted in the regulations.

Storage facility includes a cabinet, receptacle, cupboard, refrigerator or room; thalidomide means -

We believe that a storage facility include a lockable enclosure within a vehicle as most rural veterinarians would stock some scheduled poisons in vehicles for use after hours and on farm.

7 Permit required for Schedule 9 poisons

A registered medical practitioner, pharmacist, veterinary practitioner or dentist must not manufacture, sell, supply, purchase or otherwise obtain, possess, administer, use or prescribe a Schedule 9 poison unless he or she holds a permit issued under the Act or these Regulations to do so.

This should simply read "A person must not …" so that unauthorised persons are also included.

25 (7) A veterinary practitioner must not write a prescription for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison other than for the treatment of an animal named or described on the prescription.
100 penalty units.

This section needs to allow for a prescription for multiple animals (ie. a litter of puppies; livestock)

26(3) (b) the name and address of the patient for whom the prescription is intended, or if a prescription is written by a veterinary practitioner, the name or species of animal and the name and address of the owner or ther person having the custordy of the animal or animals; and

This is inadequate as it would allow for the species only or animal name only to be written on a label and the dispensing label that the pharmacist produced would be inadequate. The current requirements for veterinary labels would be better:

> "the name and address of the patient for whom the prescription is intended, or if a prescription is written by a veterinary practitioner, the species and identity of the animal(s) to be treated; ie.tag number, species, breed, age, sex and the name and address of the owner or the person having the custody of the animal or animals; and "

29 Containers of drugs to be labelled with certain details

(1) A registered medical practitioner, pharmacist, veterinary practitioner or dentist who supplies a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison for the treatment of a specific person, or the veterinary treatment of a specific animal, must ensure that the container in which it is packed is labelled with the following information-

- *a) the name of the patient or name or specifies of animal and the name of the owner or person having custody of the animal or animals; and*
- *b) the date of recording as required by Division 5; and*
- *c) the name, address and telephone number of the place of supply; and*

This regulation is for the treatment of …a specific animal … which could be read as excluding containers destined for the treatment of more than one animal which means that the pluralising of animals in (a) is inconsistent. Presumably it is meant to have scope for the treatment of more than a single animal. Suggest replacing with "veterinary treatment of a specific animal" with "veterinary treatment of an animal or animals".

Again, we suggest the terminology "species and identity of the animal(s)" rather than "name of patient or species of animal". With the latter, "Goldie" would do – which could be a fish or a dog!

29(6)(7) A veterinary practitioner is not required to comply with subregulation (1) if a Schedule 4 poison is supplied in bulk for treatment of flocks or herds of animals provided that –

- *a) Each container of the poison retains the manufacturer's original label; and*

We suggest removing the words "flocks or herds of" and just referring to "bulk treatment of animals." (Litters of puppies, stable of horses, fish, shellfish should be clearly included).

45 Use of drugs and poisons restricted to person or animal for whom they were supplied

(1) A person must not administer or use a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison supplied by a registered medical practitioner, pharmacist, veterinary practitioner or dentist for the treatment of a specific person or animal other than for the treatment of that person or animal.

100 penalty units.

The intent of this regulation is to ensure that scheduled poisons are used for the purpose for which they are supplied. However, it does not account for scheduled poisons that have been illegally supplied or obtained through the internet or via unauthorised sale.

Whilst the authority to possess a scheduled poison is covered under Regulation 5 and Section 36B(2), the unauthorised use of such a poison is a far more serious offence which entails risk to Australia's trade, animal welfare and antibiotic resistance.

The effect in agriculture is that a farmer may use an unlabelled S4 remedy on any animal, but must only use a labelled one for the purpose on the label. This is becoming a serious issue with risks to trade and welfare and we urge that serious consideration be given to it. It is suggested separating out the veterinary from the medical uses and adding the following clause:

> "A person must not administer or use a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison for the treatment of an animal unless it has been prescribed or supplied by a registered veterinary practitioner or is otherwise authorised under this Act.
> 100 penalty units.