



Australian Veterinary Association

**GUIDELINES FOR PRESCRIBING,
AUTHORISING AND DISPENSING
VETERINARY MEDICINES**

2005

NOTE

This document will be updated regularly. It is important that you have the most recent version, which is available on the internet at www.ava.com.au

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Guidelines for Prescribing, Authorising and Dispensing Veterinary Medicines (2005)
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Preface

These guidelines are based on the Therapeutics section of the previous AVA Members' Directory and Policy Compendium, together with Guideline 06: *Supply and Use of Drugs in Veterinary Practice*, Veterinary Practitioners Registration Board of Victoria.

Various appendices have been provided by Special Interest Groups of the AVA. There remains some duplication and overlap in the codes for the different species, and this will be addressed in future versions of the guidelines. It has been suggested that the future inclusion of case studies might assist in dealing with particular situations. Also, it should be noted that veterinary immunobiologicals have not been included in this version, and this will also be considered.

Individual veterinarians representing various facets of professional activity have offered useful comment, which is gratefully acknowledged. Information also has been drawn from *Antimicrobial Prescribing Guidelines for Veterinarians*, (2nd Edition) Post Graduate Foundation in Veterinary Science, University of Sydney, and relevant publications of the New Zealand Veterinary Association, Canadian Veterinary Medical Association and the Royal College of Veterinary Surgeons (UK).

Officers of Australian state/territory drug regulatory agencies kindly agreed to review the guidelines, including the list of relevant legislation, and this document incorporates their comments.

The preparation of these guidelines was initiated by the AVA Therapeutics Advisory Committee. The strong support and constructive comment from members, especially the Prescribing and Dispensing Working Group (Drs Bill Darmody, Lee Cook, Tom Grimes, Simon Hobson, Derek Major and John Plant), has been particularly helpful.

Michael Bond, Editor
20 February 2005

Abbreviations

APVMA	Australian Pesticides and Veterinary Medicines Authority
ASEL	Australian Standards for the Export of Livestock, Department of Agriculture, Fisheries and Forestry, Australian Government
PAR	Prescription Animal Remedy

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GUIDELINES FOR PRESCRIBING, AUTHORISING AND DISPENSING VETERINARY MEDICINES

1 Introduction

An important aspect in the delivery of professional veterinary services is the availability and use of a wide range of effective veterinary medicines. The significance of this professional activity is highlighted in the Australian Veterinary Association Code of Professional Conduct. **The veterinarian's authority to prescribe and supply such substances carries significant legal and ethical responsibilities.** These guidelines are regarded as the minimum standard expected from a veterinary practitioner exercising reasonable skill and care in the treatment of animals. All veterinarians should ensure they are familiar with these guidelines and the relevant legislation of the jurisdiction(s) in which they practise.

In any professional employment arrangement – as a partner, associate, locum, employee of a company etc. – **a veterinarian assumes personal responsibility** for their actions in relation to the prescribing and dispensing of veterinary medicines. In most jurisdictions veterinary practitioners who also own a drug wholesaling business are required to operate the two activities as separate entities. Again, the general principle of personal responsibility for prescribing and dispensing applies, however legal advice should be obtained regarding particular business arrangements.

Many factors can jeopardise the success of medication, for example when an infectious agent is involved, apparent treatment failure may be associated with any three components of the 'chemotherapeutic triangle' – the host, the micro-organism and the antimicrobial drug. Once a diagnosis has been made and an appropriate medication chosen, the treatment schedule must be designed to achieve an effective concentration of the drug at the target site for the required period.

The availability of potentially dangerous (toxic) drugs and poisons is restricted by law to enable their safe and effective use. The classification of drugs and poisons into Schedules 1 – 9 (under the Standard for the Uniform Scheduling of Drugs and Poisons) is based on several factors including

- toxicity,
- purpose for use,
- potential for abuse,
- safety in use and the therapeutic need for the substance.

Schedule 1. Generally substances of plant origin, available only from authorised persons, including veterinarians.

Schedule 2. Only available from a pharmacy, veterinary surgery or licensed person (where a pharmacy or veterinary surgery is not available), but can be sold from open shelves and advertised.

Schedule 3. Only sold by authorised persons including veterinarians, and cannot be advertised except as a generic drug group.

Schedule 4. Only sold (dispensed) on prescription – includes prescription animal remedies and prescription only medicines (registered for use in humans).

Schedules 5, 6, 7. Non-therapeutic chemicals in increasing order of toxicity (with some restrictions on the availability of S7 products).

Schedule 8. Substances with legitimate therapeutic uses, but which have addictive or abuse potential.

Schedule 9. Generally have no therapeutic use, and are subject to abuse. Only available for research.

[In Victoria ketamine and anabolic/androgenic steroids presently are classified in a special

Schedule 11.]

The purpose of these guidelines is to encourage the prudent and responsible use of veterinary medicines by all sectors of the veterinary profession. They are intended to provide a practical and up to date source of information related to the prescribing, authorising and dispensing of drugs, focusing on the legal and ethical responsibilities of veterinarians.

2 Definitions

In these guidelines, the following definitions apply:

Advice note

Written advice provided by a prescribing/dispensing veterinarian to a client, regarding administration of a drug, withholding period, safe handling instructions etc. in addition to the dispensing labels required on containers.

Animal

Includes mammals, birds, finfish, crustacea and molluscs.

Antibiotic

Any anti-bacterial or anti-fungal agent, including sulphonamides, trimethoprim and ionophores, but does not include any immunobiological substance. Antibiotics of direct or indirect human health significance are classed as Schedule 4 (PAR) veterinary medicines. Low-risk products are generally classed as Schedule 5 or 6.

Authorisation

A veterinary authorisation is a special type of prescription. It is an order to supply or use but it usually relates to circumstances in which:

- the prescribing veterinarian has established a routine activity or animal health program (complying with the relevant code of practice for an industry) that anticipates a use for a PAR product;
- the PAR product is to be supplied by another veterinarian; or
- a feed mill is required to provide stockfeed or premix medicated with a PAR.

Refer to Appendices 10 and 13 for sample forms.

Contraindication

A condition stated on the label that indicates a limitation on either the effectiveness or safety of the product. These only apply to veterinarians in certain states/territories if they are prefaced by the words “*DO NOT...*” or “*NOT TO BE USED...*”, and in these jurisdictions these restrictions must be observed by veterinarians and also by animal owners.

Dispensing

To supply veterinary medicines as per instructions specified in a veterinary prescription or veterinary authorisation, which includes breaking (splitting) of packages.

In relation to dispensing by a veterinarian, dispensing means:

- to supply any product, PAR or otherwise, in its original packaging or broken down into smaller quantities or volumes, which are repackaged and relabelled in accordance with state/territory legislated requirements; or
- to supply a PAR product on the authorisation of another veterinarian. [In Western Australia, a veterinarian’s prescription may only be filled by a pharmaceutical chemist or an authorised person who holds a valid Stock Feed Manufacturers Permit.]

‘Filling a prescription’ has the same meaning.

Drug

Any veterinary medicine or veterinary chemical product.

Food producing animal

Cattle, sheep, goats, pigs, poultry (including game species), buffalo, ratites, camelids, finfish, crustacea and molluscs.

Herd

Includes any group of animals.

Hormonal growth promotant

A veterinary chemical product containing a substance that is responsible for oestrogenic, androgenic or gestagenic activity to enhance growth or production in animals.

Medicated stockfeed

A ready-to-use stockfeed, or premix to be added to a stockfeed, that incorporates one or more veterinary medicines or veterinary chemical products for the purpose of medicating a group of animals via the stockfeed.

‘Off-label’ use

The use of a veterinary medicine to treat an animal in a way that is not described on the registered label, including a change in the species, dose rate, frequency or duration of use, or withholding period.

Premix

A manufactured mixture of active ingredient(s) and carrier designed for direct inclusion into the bulk ration of animals.

Prescribing

The act of specifying in writing a treatment and its use regimen. Only a veterinarian may prescribe a prescription animal remedy.

Prescription

A prescription is a documented order to supply a PAR product when the product is not supplied immediately by the prescribing veterinarian. It must be written and contain all the information required by law and good veterinary practice. While the form of a prescription may vary it must:

- be readily recognisable as a prescription;
- contain the essential information; and
- be legible and sufficiently clear and unambiguous to allow an approved person to dispense or fill the prescription. Refer to Appendix 12 for a sample prescription form.

Prescription animal remedy (PAR)

Veterinary medicines included in poisons Schedule 4 that may only be supplied to, and must be prescribed by, a registered veterinarian in the practice of their profession for the treatment of animals. Persons and businesses distributing, wholesaling or retailing PARs must be licensed by the relevant state/territory health department. Most antibiotics used therapeutically in animals are classified as PARs (S4s).

Prophylactic use

The use of a veterinary medicine, by any route of administration, to prevent infection with a pathogen(s) that is anticipated to challenge the animal(s) or cause disease during the treatment period. That is, initiating treatment in advance of an actual infection or disease condition because such a condition is expected to occur if treatment is withheld.

Restraint (Label restraint)

An absolute prohibition printed on the label which can cover a range of issues. Those prohibitions which appear under a “*Restraint/s*” heading apply to veterinarians in all jurisdictions, and prohibit any ‘off-label’ use in contravention of that statement. Other restraint statements (simply prefaced by “DO NOT ...” etc.) only apply in certain jurisdictions (Northern Territory, Queensland and Victoria) or for treatment of food producing animals (New South Wales).

Therapeutic use

The use of veterinary medicines for the purpose of treating an existing disease condition or injury.

Veterinary medicine (or veterinary chemical product)

A general term, meaning a substance or mixture of substances that is supplied or used for administration to an animal, by any means, as a way of:

- preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest*;
- curing or alleviating an injury suffered by the animal;
- modifying the physiology of the animal so as to alter its natural development, productivity, quality or reproductive capacity; or to make it more manageable; or
- modifying the effect of another veterinary medicine.

[* In NSW, any veterinary chemical product applied externally to kill external parasites is regulated under the Pesticides Act 1999 and is not subject to the veterinary use provisions of the Stock Medicines Act.]

3 Legislation

Veterinarians must be familiar and are expected to comply with the current Commonwealth and state/territory legislation relating to the supply and use of veterinary medicines and pesticides. The rules in different jurisdictions can vary – see section 32 for links to relevant websites.

State and territory drugs and poisons legislation authorises registered veterinarians to obtain and use, supply, order, authorise or prescribe Schedule 4 and 8 drugs (and sometimes drugs from other schedules depending on the legislation in the relevant jurisdiction). With this authority comes a clear responsibility to comply with the legislation and to act in a professional manner. Each state/territory also has legislation controlling the use of veterinary drugs or chemicals which further delineates the duties and responsibilities of veterinarians in the supply and use of drugs and veterinary chemicals (control-of-use of agricultural and veterinary chemical legislation).

It should be noted that in some jurisdictions, legislation covering use of veterinary chemicals in aquaculture is ill-defined and incomplete. Veterinarians prescribing drugs for use in finfish, crustacea and molluscs are advised to review the legislation applicable to their situation.

Important! Any breaches of the relevant drugs, poisons and controlled substances legislation, the agricultural and veterinary chemicals legislation and of these guidelines, could constitute unprofessional conduct.

4 Special classes of drugs

Drugs that fall into the categories of Schedule 4 (prescription animal remedy or prescription only medicine) or Schedule 8 (controlled drugs) may not be held for supply, supplied authorised or prescribed by a person other than an 'authorised person'. Drugs and poisons legislation in each state/territory designates registered veterinarians as 'authorised persons'.

Anabolic steroids. Injectable anabolic steroids should only be administered by the attending veterinarian. Repeat quantities and administration intervals should be noted on the clinical record.

Cytotoxic (anti-neoplastic) drugs. Cytotoxic drugs include a wide range of therapeutic agents intended primarily for the treatment of cancer. They are highly toxic to cells, and many have proved to be carcinogens, mutagens or teratogens. Adverse health effects may result from occupational exposure, and appropriate risk management strategies should be implemented – see Appendix 8.

Extemporaneous prescription/formulation. A veterinary chemical preparation specially formulated by a veterinarian or by a pharmacist on a veterinarian's prescription for the treatment of a specific condition in an animal(s) under the veterinarian's care. Such unregistered products may only be used in food-producing species when the drug is compounded for treatment of an individual animal.

General anaesthetics. Although not specifically prohibited by state/territory legislation, there are no legitimate indications to dispense injectable general anaesthetics in veterinary practice.

Hormonal growth promotants (HGPs). Specific controls have been imposed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) which require all suppliers of hormonal growth promotants, including veterinarians, to be licensed by the APVMA. Such licensed suppliers are subject to annual audits and must obtain purchaser declaration forms and keep detailed records of all HGP purchases and sales, and provide monthly sales returns.

See <http://www.apvma.gov.au/qa/hgp.shtml>

There are particular requirements if animal products are intended for export to the European Union – see

<http://www.affa.gov.au/content/output.cfm?ObjectID=13C0E15F-A8FB-45C4-9F908A2861C0C7F6&contType=outputs>

Natural products. Any product containing ingredients derived from natural sources that is administered to animals with claims of modifying health, production, performance or behaviour must be registered. Products containing glycosaminoglycan, chondroitin sulphate, glucosamine or similar substances (including shark cartilage, abalone or green-lipped mussel) are considered to be veterinary medicines.

Prostaglandins. Prostaglandins present particular health hazards to humans and administration by veterinarians is preferable. However if prostaglandins are dispensed, it should only be to experienced operators, with clear instructions about handling precautions. State veterinary board directives on prostaglandin dispensing should be followed.

Psychotropic drugs. Various registered (human) anti-depressants such as fluoxetine, selegiline and amitriptyline are now used to treat behavioural problems in dogs, cats, birds and horses. These are mostly 'off-label' uses, which must be carefully explained to clients – see section 22.5. In prescribing and dispensing these drugs, veterinarians also should be aware of the potential for illegal diversion to human use.

Sedatives for clipping, shoeing, horse-breaking, deer velveting and other procedures performed by non-veterinarians. Sedatives should be dispensed only

to experienced operators for use in animals under the care of the prescribing veterinarian and in doses appropriate for the immediate need. Hazards of sedation to the animal and the operator should be clearly explained.

Aquaculturalists commonly use sedatives to sample, grade and move stock (finfish and molluscs). There is only one product registered for this purpose, and another that is available under a 'minor use' permit from APVMA. Both products should only be supplied by prescription.

5 Prescribing, Authorising and Dispensing (PAD) checklist

The prescribing, authorising and dispensing of medicines is a professional service provided by registered veterinarians. The criteria listed in the Prescribing, Authorising and Dispensing (PAD) checklist on the following page should be applied to the prescribing, authorising or dispensing of all restricted drugs.

It is suggested that this checklist could be copied for display in veterinary pharmacies and inclusion in clinical records as appropriate.

Veterinarians should ensure that the information and instructions provided when prescribing, authorising or dispensing veterinary medicines are complete, accurate and up to date. The product label and the entry in the IVS Annual might not be up to date, and current information is available on the APVMA website <http://www.apvma.gov.au/> or from commercial sources such as *Infopest* (Queensland DPI&F) or *Infinder* (South Australia, PIRSA).



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Prescribing, Authorising and Dispensing (PAD) Checklist

Veterinarians should use this checklist whenever prescribing, authorising or dispensing (supplying) drugs, and are advised to include the PAD checklist in the clinical record if prescribing, authorising or dispensing occurs in any circumstance other than a fully-documented clinical examination.

BEFORE

- prescribing and dispensing a Schedule 4 (PAR) or 8 (Controlled) drug,
 - prescribing and dispensing any other veterinary medicine whether registered or not,
 - authorising or prescribing a veterinary medicine for inclusion in a stock feed or premix,
 - authorising or prescribing 'off-label' use of a registered drug or veterinary medicine, ensure that the following conditions are met:
- The person presenting the animal(s) is a *bona fide* client.
 - I have current knowledge of the management, health status and drug status of the animal(s) and am satisfied there is a therapeutic or prophylactic need for the use and/or supply of this drug.
 - I have followed the requirements of the drugs and poisons and control-of-use legislation in my state/territory in regard to:
 - the ordering, purchase, storage, use and supply of this product (including any 'off-label' use),
 - the use of appropriate containers,
 - labelling requirements, including the provision of advice notes,
 - recording requirements (including any guidelines from my professional registration body).
 - I am confident the client understands my instructions regarding the use and storage (and where appropriate, identification of treated animals and relevant withholding restrictions) of this drug, and is able to use it properly and safely.
 - The amount I am prescribing/dispensing is reasonable for treatment of the condition for which I have documented the therapeutic need.
 - If the drug is an antibiotic, I have considered the expected infectious agent, spectrum of activity of the drug and implications of antimicrobial resistance.

6 Veterinarian-client relationship*

A *bona fide* veterinarian-client relationship exists where each of the following occurs:

- The veterinarian has assumed responsibility for making judgments regarding the health and welfare of the animal(s) and the need for treatment, with the owner's (client's) agreement.
- The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of their medical condition. This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of a clinical examination, or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- The veterinarian is available, or has arranged for adequate emergency coverage, for follow-up evaluation in the event of an adverse reaction or failure of the treatment regimen.

The care of the animal or herd by the veterinarian should be real and not merely nominal, i.e. there must be evidence of personally having contact with the animal/herd for diagnosis and treatment and of assuming personal responsibility for the diagnosis, treatment and outcome.

The veterinarian should know the client and have clinical records relating to the client's animal(s). In the case of a new client, the veterinarian should personally familiarise him/herself with the client and their animal or herd (by establishing the clinical history and performing appropriate clinical and pathological examinations), and commence keeping appropriate records, prior to dispensing restricted drugs.

Associates and locums working in the practice can deputise for the veterinary practitioner provided they have unrestricted access to the client's records.

A client may have a *bona fide* professional relationship with more than one veterinarian, or more than one veterinary practice. When dealing with a request for dispensing from a client with whom the veterinarian does not have a current professional relationship it is advisable to ask the client if they have a current professional relationship with another veterinary practitioner. Having established the current veterinary provider, a veterinarian is then in a position to either refer the client back to that provider and/or establish a current *bona fide* professional relationship.

A veterinarian must be registered to practise in the state/territory in which the animal or herd is located.

Important! A *bona fide* veterinarian-client relationship is the basis for the supply of veterinary drugs to animal owners and custodians. Veterinarians should carefully assess each situation, to ensure that the above criteria have been satisfied, before drugs are prescribed, authorised and dispensed/supplied.

* This definition is from the AVA Code of Professional Conduct, and is adapted from the Royal College of Veterinary Surgeons and the American Veterinary Medical Association codes.

7 Therapeutic need

The administration of any medication can produce a range of harmful effects, including:

- selection or promotion of antimicrobial resistance;
- hypersensitivity reactions;
- direct tissue or organ toxicity,
- toxic interactions with other drugs;
- interference with the protective effect of normal host microflora;
- tissue necrosis at injection sites;
- impairment of host immune or defence mechanisms; and
- production of residues in animal products for human consumption.

When presented with a particular case, a veterinarian is required to establish the therapeutic need for any treatment regimen.

There should be clinical justification and documentation for the therapeutic need. This should include a record of clinical examination, any laboratory test results, radiographs etc, and record of diagnosis and consideration of appropriate therapies.

Prophylactic antimicrobial use in surgery

Prophylactic antimicrobial drugs in surgery are not indicated for routine, aseptic surgery of less than 90 minutes duration where no pre-existing infection is present, the gastrointestinal, female reproductive or respiratory systems have not been invaded, and aseptic technique is maintained. However, the use of antibiotics in a prophylactic manner may be justified in situations such as operative procedures in the field, dental procedures with associated bleeding, patients with leucopenia, contaminated surgery, or where the consequences of sepsis would be potentially irreversible, life-threatening or likely to cause prolonged pain or suffering.

For antibacterial chemoprophylaxis, drugs should be administered before the procedure so that adequate concentrations are present *in vivo* at the time of surgery - for best effect the drug must be present in the wound before contamination occurs. The likely contaminating pathogens should be considered when selecting the appropriate antibacterial drug to use prophylactically.

Antimicrobial prophylaxis is less effective if the contamination of the surgical site includes certain particulate matter. Where contamination has been present for three or more hours, benefits of antibiotics may be reduced.

8 Species knowledge

When prescribing, authorising and/or dispensing drugs it is the responsibility of a veterinarian to ensure that they have adequate knowledge of the species involved. Where this is not the case they should consider obtaining advice from a colleague with the required knowledge or referring the client to a specialist or more experienced colleague.

9 Records

Adequate clinical records (in hard copy or electronic form) are required to justify and demonstrate diagnosis, therapeutic need and that the animals are under the veterinarian's care. Whenever appropriate, the PAD checklist (section 5) should be included in the clinical record. The records should indicate that the veterinarian has authorised the dispensed drugs and include the outcomes of treatment and follow-up.

If a prescription or advice note is issued for a dispensed drug or medicated feed or premix, a duplicate should be retained by the veterinarian. State/territory legislation may also require such records to be kept. Records of 'off-label' prescription, use or supply for food animals should be kept, including any details required by state/territory legislation.

10 Outcome of treatment and after-care

There should be adequate after-care and follow-up to determine whether the expected outcome of treatment has been achieved, and to review treatment if the expected outcome is not fully achieved. Follow-up is important. It completes the clinical history, ensures that the treatment regimen was appropriate, enhances the veterinarian's experience and training, alerts the veterinarian to any unexpected outcomes or side-effects of the medication, allows for monitoring of a client's drug supplies and for the collection and correct disposal of any unused drugs. Above all, it demonstrates the veterinarian's concern for animal welfare.

Reporting of adverse drug reactions to the manufacturer and to the APVMA through the Adverse Experience Reporting Program (<http://www.apvma.gov.au/ga/aerp.shtml>), should be undertaken by the veterinarian in any case where an unexpected or adverse reaction to a drug may have occurred.

In some cases an animal or herd may be treated by more than one veterinarian, e.g. in a breeding herd where the regular attending veterinarian and an unassociated veterinarian with a particular interest in reproductive management are both involved. In such cases, there should be clear agreement between the different veterinarians to provide specified after-care and follow-up.

Agreement between such practices is sometimes difficult, but all attempts to reach agreement should be made for the benefit of the client and the animals, and to ensure that each veterinarian has current knowledge about the health and treatment status of the animals.

11 Client understanding and competence

The veterinarian is expected to have knowledge of the individual client and their husbandry and treatment management, knowledge, skills and ability to understand instructions and correctly administer drugs. This is a pivotal reason for the requirement that dispensing of drugs occurs only to *bona fide* clients. It assumes that the veterinarian will be able to fully inform the client regarding proper use of the drug, including dosage, route and method of administration, possible side effects and withholding periods or export slaughter intervals. For farmed animal species, the latter information is critical, and the veterinarian should provide clients with regular updates. For example, cattle and sheep data are available from Meat

and Livestock Australia <http://www.mla.com.au> (Click on *Livestock Quality Systems*, then *Chemical Usage Management*.)

In the case of drugs which can be dangerous to handle (e.g. prostaglandins, tranquilisers, local anaesthetics, or euthanasia agents), it may include informing the client of any special restrictions on who is to handle the drug and how it is to be handled. Ancillary handling aids, e.g. latex gloves, can be provided with such drugs, and the importance of their use carefully explained. It is imperative in such cases that the veterinarian is confident the client is able to safely and effectively use the product, that they will follow the instructions on the dispensing label and that they understand their importance. Any specific instructions about the administration of the drug should be included in an advice note, and a copy kept in the clinical records. In some jurisdictions intravenous injection is considered a restricted act of veterinary science/surgery and products for intravenous use should not be supplied.

Veterinarians have to satisfy themselves that it is reasonable to supply a particular drug, if requested by the client, rather than the veterinarians themselves administering the drug. With many drugs this will not be the case.

Where a drug is dispensed to a 'proper responsible agent' – see section 28, the veterinarian must also be satisfied as to the competence of that person.

12 Amount dispensed

The quantity of drugs dispensed must be commensurate with the therapeutic need. The veterinarian should take all reasonable steps by way of accurate record keeping and checks of those records, to ensure that the drugs supplied were likely to have been used only for the specific purpose intended. Where a client is using a PAR on a regular basis, a record of that usage should be kept – see Appendix 11.

It is not generally acceptable to dispense quantities of drugs for a client to have on a contingency ('just in case') basis. If a client requests drugs for such an anticipated need it is the responsibility of the veterinarian to apply the PAD standards – see section 5. [This does not apply to secure stores of scheduled drugs, which might be maintained by an authorising veterinarian at location(s) distant from the veterinarian's normal premises, for example intensive animal production enterprises – see sections 25 and 28.]

The requirements of after-care and follow-up are vital in this context, and an agreement should be made with the client for follow-up in a reasonable time to monitor the use of the drugs and the outcome of treatment. Consideration should be given to the retrieval of any unused drugs for proper disposal, which does not imply that a refund of the cost of drugs needs to be considered. Rather it is to ensure that clients are not left in possession of indeterminate amounts of unused drugs, which may deteriorate or become out of date, or which the client may be tempted to use for other (undiagnosed) conditions, and to ensure that all disposal of drugs is done correctly.

Important! For 'off-label' use or supply for food-producing animals, the responsibility for advising on withholding periods, export slaughter intervals and exact dose of the drug for the specific condition rests with the veterinarian for each case in which the drug is used. This control cannot be achieved if drugs are used for conditions other than those for which they were supplied. The occurrence of unacceptable residues as a result of over-prescribing/dispensing may place the veterinarian in a legally-vulnerable position.

13 Remote locations

It is recognised that in a few particular situations, such as the extensive pastoral industry and some aquaculture establishments, it might be appropriate for a veterinarian to prescribe, authorise and/or dispense a limited supply of a drug as a contingency measure. There might be a high probability of an annual recurrence of a specific disease condition on a remote property, for example. In such situations, the veterinarian should be especially aware of the need to satisfy the PAD checklist criteria as far as feasible, maintaining appropriate communication with the client. The use of digital images transmitted on the internet might be helpful in establishing a diagnosis.

Another example is the treatment of animals in remote indigenous communities, where a specified individual ('proper responsible agent') may be required to administer prescription animal remedies as a prophylactic measure.

A special situation exists with aquaculture, where clinical expertise may not be available locally. If a veterinarian is consulting to an aquaculture establishment interstate, veterinary medicines can be supplied through a local veterinary practice, or the consultant could supply the drugs direct.

Whatever the circumstances, the veterinarian should be satisfied that the person describing any symptoms and administering treatments is capable and competent.

Any drugs supplied should be labelled with the veterinarian's name and practice address, owner's name, species of animal, date, instructions for use and the words '*For emergency use as directed*'. The veterinarian should keep detailed records of any communications regarding observations made by the custodian of the animal(s), directions for treatment etc. In addition, the veterinarian should require that the custodian maintains a written record of all medication administered under their supervision.

Sending by post or courier

On occasions it might be necessary to send restricted drugs by post or courier. The labelling, packaging, addressing and dispatch are an integral part of the dispensing process and should be closely supervised by the veterinarian. Wherever possible, receipt of the drugs should be confirmed and recorded – see section 22.6.

Livestock exports

For livestock export consignments by sea that are not accompanied by a veterinarian, in most jurisdictions, limited quantities of restricted drugs can be prescribed/authorised/dispensed as a contingency measure. This should be in

accordance with the Australian Standards for the Export of Livestock (<http://www.daff.gov.au/livestockexportstandards>); the amounts of the various drugs required are listed under Standard 4, *Vessel preparation and loading*, Tables A 4.1.7 and 4.1.8 (see also section 28).

The air transport of animals, particularly horses, and the supply and use of PARs in the absence of an accompanying veterinarian is a vexed issue. The Australian Equine Veterinary Association has highlighted the legal and ethical problems involved, if restricted drugs are made available to grooms who have limited training and no accreditation. In these circumstances, veterinarians who are asked to prescribe and supply drugs for such use are advised to consider the potential legal and ethical implications.

14 Animal welfare

It is the veterinarian's responsibility to ensure that animal welfare is a primary consideration when prescribing, authorising, dispensing and using drugs.

15 Veterinarians' lawful entitlement

A registered veterinarian is authorised to obtain, possess, use or supply most drugs for the lawful practice of their profession, but within the specific limitations described below. The authorisation is limited to the treatment of animals under the veterinarian's care and, where a prescription or authority is written, only applies to the person having charge of the animal(s) or the manager of a licensed feed mill or premix supplier.

16 Wholesaling

Generally, a registered veterinarian must not sell drugs by wholesale, unless they have the appropriate licence.

Wholesaling involves selling to other authorised persons for the purposes of on-trading. A veterinarian must not supply or prescribe drugs on the request or order of another person in a situation where they have not personally satisfied the requirements of the PAD checklist – see section 5.

The supply of a Schedule 4 drug by a veterinarian, on a written order or authorisation issued by another veterinarian, is an appropriate activity, comparable to the filling of a prescription by a pharmacist. The label should include the details of the supplying practice, but should indicate that the product was supplied on the order of the authorising veterinarian. Appropriate records should be kept of such supply.

It is primarily the responsibility of the authorising veterinarian to ensure that the PAD checklist criteria are met.

The bulk purchase of drugs by a number of separate veterinary practices should not be regarded as wholesaling, providing there is no on-selling outside the purchasing group. Likewise, the emergency supply to a neighbouring practice or a travelling veterinarian should be treated as supply by authorisation. Such transactions should be fully documented.

17 Retailing

Sale by retail in a conventional shop by a non-veterinarian is limited to Schedule 5, 6 and some Schedule 7 poisons, and requires supply in the original unopened package as supplied by the manufacturer. Veterinarians may be able to dispense most of these products, depending on particular state/territory legislation.

18 Self-administration

Self-administration of drugs of addiction by veterinarians is prohibited in all jurisdictions unless they have been prescribed by a registered medical practitioner or registered dental practitioner for treatment of the veterinarian. In some jurisdictions the same restrictions apply to all Schedule 4 drugs, and local regulations should be checked.

19 Containers

Containers for drugs dispensed in other than the manufacturer's packaging must be impervious to the contents, sufficiently sturdy to prevent leakage, be securely closed and capable of secure re-closure if required for more than one use. Child-proof containers generally are not required for dispensed drugs, except for a small number of concentrated volatile oils such as melaleuca oil. However, if drugs are supplied to a veterinarian with such a closure it would be prudent to dispense them with a similar closure.

The following human drugs require child-proof containers, which can include foil strips, when dispensed:

anti-arrhythmics (eg verapamil), anti-convulsants (eg phenytoin), anti-histamines (eg chlorpheniramine), aspirin, beta-blockers (eg propranolol), calcium antagonists, digitalis glycosides, diphenoxylate hydrochloride, iron compounds in high concentrations, methadone, methyl salicylate liquid, MAO inhibitors, narcotic analgesics, paracetamol, phenothiazines (eg chlorpromazine), sulphonylureas, theophylline and anti-depressants.

See Therapeutic Goods Order No. 65 *Child-resistant packaging for Therapeutic Goods*. <http://www.tga.gov.au/docs/html/tgo/tgo65.htm>

In Victoria child-proof containers are required for drugs such as antihistamines and chemotherapeutic agents. Veterinarians should be aware of legislative requirements in their jurisdiction.

A container on which the name of any registered drug or poison is embossed or otherwise permanently marked must only be used to contain that substance. It is preferable that all labels be printed and not hand-written.

A paper or plastic bag or envelope, or a cardboard box should not be used as a container for a restricted drug whether dispensed or not, unless that drug is also contained in individually sealed and measured amounts, eg foil strip packaging. Wherever appropriate, plastic vials should be used when dispensing tablets. Feed premixes are usually packed in polyethylene bags within a paper bag.

Only a veterinarian or a person acting under their instruction is permitted to divide ('break') packs of veterinary chemical products to dispense the contents to clients. [Note that in some jurisdictions, veterinarians are not permitted to divide pesticide products.] A veterinary chemical product must be supplied in a container that

bears all the information required on the approved label. Note that the APVMA now does not allow the use of dispensing envelopes to be part of the approved label suite of a registered veterinary product. However veterinarians are permitted to use them if supplied by a manufacturer. In this case, the dispensing envelope is considered to be 'marketing material'.

20 Waste disposal

The disposal of unwanted or expired pharmaceutical drugs and veterinary biologicals is an emerging environmental issue. All medications applied externally, injected or ingested (and their bioactive transformation products) have the potential to be excreted or washed into the sewage system and from there discharged into the aquatic or terrestrial environments. Veterinarians should make every effort to ensure these products are properly disposed of.

ChemClear

ChemClear[®] is the national chemical waste disposal program for the safe management of unwanted rural chemicals. Chemicals are classified by *ChemClear* into two groups:

- Group 1 chemicals to be accepted free of charge are:
 - sold only by member companies of Avcare (the National Association for Crop Production and Animal Health) or VMDA (Veterinary Manufacturers and Distributors Association) or participating non-members;
 - registered agricultural and veterinary products, or products whose registration has ceased since the last *ChemClear* collection;
 - in the original non-returnable rigid metal, plastic or cardboard container;
 - identifiably labelled with the original manufacturer's label or other permanent identification;
 - not collectable under any other return program;
 - not part of any special mandatory or voluntary phase out; and
 - not part of any recall where the deadline has expired.

- Group 2 chemicals for which fees are payable are:
 - agricultural and veterinary chemicals whose registration expired more than two years ago;
 - farm chemical products of non-Avcare or non-VMDA member companies that are either currently registered or whose registration or permit ceased since the last collection.

Under this program, 200mL or more of any rural chemical will be accepted. Contact 1800 008 182 for assistance in dealing with any unidentifiable chemicals or to book a collection. Bookings are essential, and can also be made at the website <http://www.chemclear.com.au>

There are differences between jurisdictions regarding requirements for disposal of waste veterinary chemicals not included in the *ChemClear* program, and veterinarians are advised to seek specific advice from their health department and/or environment protection authority.

Other Waste

In general, with the exception of Schedule 8 drugs, pharmaceutical waste should be disposed of in the same manner as clinical (hazardous) waste, i.e. with clinical waste or with sharps. Schedule 8 drugs may not be collected and/or disposed of by others, but must only be destroyed by, or surrendered to, health department staff or a police officer, who will annotate your S8 drug register.

Unexpired and unopened packages can, in some cases, be returned to the wholesaler/supplier.

In some cases local hospitals may be prepared to add veterinary wastes to their own waste, or pharmacies which dispose of unused product may be willing to take certain types of veterinary products.

In many larger centres there are commercial firms that collect and properly dispose of biomedical and hazardous wastes for a fee – see ‘Waste Reduction and Disposal Services’ in the Yellow Pages.

Sharps

Sharps (hypodermic needles, scalpels, broken ampoules and broken bottles) require particular care before disposal. They should be placed in a container at the site of use in a manner which should not incorporate cutting, bending or manipulation which may release aerosols or splatter contaminated fluids. Needles should not be clipped, broken, bent, recapped or otherwise manipulated by hand.

The sharps container should be:

- clean, puncture-resistant, leak-proof, shatter-proof and able to withstand heavy handling;
- clearly labelled with the nature of the contents, distinctively coloured and displaying the universal biohazard label;
- labelled ‘*CLINICAL WASTE*’.

Aquaculture

Waste disposal is a critical issue in aquaculture, especially where effluent from the farm is passed directly into the environment. As veterinary medicines are often administered in the feed, a potentially serious environmental issue can be created, with chemicals being leached directly from the feed or excretion of a proportion of the active ingredient. Current environmental controls do not appear to adequately address this issue.

21 Use of the internet

The increasing use of the internet for commercial transactions presents various perceived opportunities for obtaining and supplying veterinary medicines. A range of drugs is now being advertised on websites in Australia and overseas.

If a client wishes to purchase drugs on the internet, a veterinarian may choose (or not) to write a prescription. The prescription should refer to a particular animal(s) and satisfy the PAD checklist criteria. However, the client and veterinarian may have to consider several important issues, including:

- While there is some 'mutual recognition' for prescriptions across state borders, an Australian prescription might not be valid overseas.
- The drug requested on the internet may not be available under the same brand or composition as registered for use in Australia.
- A person must not import an unregistered veterinary chemical product into Australia, without written permission of the APVMA.
- Australian Customs' import restrictions often require permits and payment of duties when goods arrive.
- Health officials may intercept the consignment, to determine the type of medication and its possible uses.
- An overseas product may not have passed the stringent assessment and registration procedures required by the APVMA.

While a registered veterinarian has the authority to obtain and supply restricted substances, the Commonwealth Agricultural and Veterinary Chemicals (Administration) Act 1992 and the Therapeutic Goods Act 1989 require that permits be obtained to import most chemical products, animal or human. Again, the above points are relevant.

It is unacceptable for a veterinarian to write a prescription (to be filled on the internet) for food producing animals, unless it can be guaranteed that the product is to be supplied from within Australia. Otherwise, it may not be possible to provide appropriate advice regarding withholding periods etc, if the exact product specifications are not known.

The use of the internet for advertising or wholesaling drugs is a strictly regulated area, and veterinarians are advised to exercise caution. Advertising about veterinary medicines may contravene the Agricultural and Veterinary Chemicals Code Act 1994. Advertising of PARs to anyone other than veterinarians is prohibited in all jurisdictions – see section 22.8. In all jurisdictions a licence is required for wholesaling, and this would be a separate business unrelated to a veterinary practice - see section 16.

22 Schedule 4 drugs

Schedule 4 drugs bear the manufacturer's label stating "*PRESCRIPTION ANIMAL REMEDY*" or "*PRESCRIPTION ONLY MEDICINE*" (if human drugs). Examples are: local and general anaesthetics, antibiotics, antihypertensive agents, benzodiazepines, corticosteroids, diuretics, some analgesics, muscle relaxants, neuroleptics and most, but not all, non-steroidal anti-inflammatory drugs (NSAIDs).

22.1 Ordering and purchasing

Schedule 4 drugs may only be ordered by and supplied to a registered veterinarian in his or her own name. Payment can be made by an employer but the veterinarian must be personally responsible and accountable for the storage and use of the drugs.

22.2 Storage and handling

Schedule 4 drugs should be stored in a secure facility (room, receptacle, cupboard, drawer or refrigerator) to which members of the public and unauthorised persons cannot gain access. There may be differences between jurisdictions which should be checked with your state/territory health department. A veterinarian can, however, leave Schedule 4 drugs with a responsible veterinary nurse or assistant provided the drug has been properly dispensed and written instructions are given concerning the use or administration for a specific animal(s).

In most states/territories it is not permissible for a non-veterinarian employed by a practice to be given possession of a dispensed Schedule 4 drug for delivery to a person in charge of the animal patient. The drug should be handed over by a veterinarian. However in some jurisdictions delivery by an employee may be permitted, provided the Schedule 4 drug has been properly labelled and is in a sealed package with the name of the person in charge of the animal appearing on the package.

Schedule 4 drugs stored at a branch practice should be secured in a locked cupboard or room, if a veterinarian is not in attendance.

In some circumstances, eg intensive production or aquaculture enterprises, quantities of Schedule 4 drugs may be stored by an authorising veterinarian at locations distant from the veterinarian's normal premises. Conditions for the supply and use of such drugs are explained in sections 25 and 28.

22.3 Prescribing

Prescribing is the act of writing a prescription for a client to have filled, generally by a registered pharmacist. [In the intensive livestock industries, pharmacists usually are not involved in filling prescriptions for feed or water medications – see section 22.4 below.]

Prescriptions must, in accordance with relevant state/territory regulations, be written in ink and signed with the prescribing veterinarian's usual signature. The PAD checklist criteria (section 5) should be satisfied before a prescription is issued. Refer to Appendix 12 for a sample prescription form. [The ability to generate and print prescriptions by computer is being pursued in several jurisdictions. February 2005]

22.4 Authorising

Authorising, which may include prescribing in some jurisdictions, is the act of writing an order or prescription for a client to have a medicated feed or premix formulated by a licensed feed mill or premix supplier, or to permit 'off-label' use of any product – whether an S4 drug or not – on livestock.

Registered veterinarians acting within a *bona fide* veterinarian-client relationship may authorise the supply of drugs in premixes or feeds by an authorised feed mill. Such authorities must be written or printed in ink and signed with the registered veterinarian's usual signature. The *Order for Medicated Feed* (Appendix 10) meets these requirements. Two copies should be supplied – one for the client, which

provides the directions for use, the other for the feed mill. A file copy should be retained.

In-feed antibiotics are purchased by feed mills from wholesalers, premix suppliers or retailers and S4 antibiotics authorised for use in feed by the veterinarian responsible for the animals using an *Order for Medicated Feed*. Water medications are ordered by the veterinarian responsible for the animals in his/her name (but usually not paid for by the veterinarian) and are usually supplied to the veterinarian (at the practice office or to the veterinarian's secure S4 drug store) by a retail distributor.

The criteria of the PAD checklist must be satisfied. See also section 25.

22.5 'Off-label' use

'Off-label' prescribing is writing a prescription or authorisation to a client to allow them to use a registered drug or veterinary chemical in a manner outside the range of uses permitted by the approved label directions - including species of animal, dosage, treatment interval etc. (but not contrary to a specific label restraint - see section 22.6).

Veterinarians are permitted to exercise professional judgement in the 'off-label' use or supply of most drugs or other veterinary medicines. This gives veterinarians access to beneficial drugs which may be registered for human use or which have limited registration for veterinary use. However, veterinarians must be aware that access to such drugs is the subject of concern in the community, and that misuse of such drugs may lead to withdrawal of this authority.

Legal limits

A number of legal limits have been placed on the 'off label' prescribing of drugs by veterinarians under national control-of-use principles adopted by most states and territories. These primarily relate to treatments for defined food-producing species (excluding horses), and are less stringent for companion animals. In most jurisdictions use of any product for companion animals is permitted, but supply for their treatment is usually restricted to human pharmaceuticals or products compounded by the veterinarian or on the veterinarian's prescription.

These limits generally include:

- A ban on the use of unregistered products, including agricultural chemicals, to treat food-producing animals, with the exception of single animals. (Definitions of which animals are food-producing vary by jurisdiction and relevant legislation or orders should be consulted.);
- A limitation on 'off-label' use, prescribing or authorising for food-producing animals of drugs and other veterinary chemicals unless they are already registered in at least one major food producing species;
- A ban on use (or prescription/authorisation) contrary to any instructions under a "Restraint(s)" heading on a product label – see section 22.6;
- A requirement to ensure all treated animals are adequately identified, sufficient to last until the expiry of any relevant withholding period;
- A ban on formulating, dispensing or using a veterinary chemical, registered for oral or external use, as an injection.

[In Queensland, if there is no 'major trade species' (which includes any food producing animals) listed on the label, only a single major trade species animal may be treated 'off-label'. For animals other than major trade species, registered products can be used 'off-label'.]

Food producing animals

Specific drugs for which there are 'off-label' restrictions in food-producing animals include:

- Chloramphenicol to treat any food-producing animals, including horses;
- Diethylstilboestrol in livestock;
- Virginiamycin - [It has been proposed that use as a growth promotant be prohibited, and its therapeutic or prophylactic use in food-producing animals limited to 21 days in any chicken broiler flock and 28 days for cattle and sheep treatment in any 12-month period. Veterinarians should check the current situation.];
- Phenylbutazone - Not recommended for use in cattle due to persistence in tissues, and consequent residue problems;
- Triclabendazole - Not recommended for use in lactating dairy cows, unless milk can be withheld from human consumption for an extended period. In most jurisdictions, this use is a specific restraint, and therefore prohibited.
- Aminoglycosides (gentamicin, neomycin, streptomycin) - Sequestration in kidneys, with consequent residue or toxicity problems.
- Sulphonamides - Parenteral administration of potentiated sulphonamides can produce high tissue levels, with consequent risk of residues.
- Colloidal silver - Not registered as a treatment for mastitis.
- Many companion animal antibiotics contain specific label prohibitions against use in food producing animals and these restrictions must be observed (other than for single animals).

A range of other restrictions apply in each jurisdiction and the relevant state/territory legislation should be consulted – see section 32.

The veterinarian assumes full responsibility for the use of any drug contrary to the drug's registered use pattern as reflected on the manufacturer's label.

If using drugs in any manner outside the range of uses permitted by the manufacturer's label or product insert, it is essential to inform the client of this, the reasons for the choice of drug, any other options available to the client and to document the informed consent of the client in the clinical records.

Use of unregistered chemicals or human medicines in food-producing animals should be limited to those cases where appropriate veterinary drugs do not exist or where they are known, or can reasonably be anticipated to be, ineffective. Legislation in most jurisdictions restricts such treatment or supply to single animals only – Consult the relevant legislation for the local definition of 'single animal'.

It is unacceptable to use a human medicine for common disease conditions in food-producing animals where approved veterinary drugs e.g., antibacterials, anti-inflammatory agents etc, are available. A veterinarian assumes full responsibility when an unregistered chemical or human medicine is used rather than a registered veterinary medicine.

'Off-label' use in food-producing animals should only be considered when:

- a careful diagnosis and evaluation of the condition for which the drug is to be used has been made;
- the veterinarian is operating within the bounds of a valid veterinarian-client relationship;
- a deliberate determination is made that there is no other appropriate veterinary drug available, ie. there is no marketed veterinary drug specifically labelled for the disease condition to be treated or the veterinary drug has been found clinically (or in laboratory tests) to be ineffective by the veterinarian in the animals to be treated;
- in the case of food-producing animals, adequate steps to prevent the occurrence of illegal residues in edible animal products have been taken. This should include a review of the best available toxicological and tissue distribution and tissue residue depletion data and establishment of an appropriately long withholding period, to ensure that no detectable residues will occur. The animal owner or manager should be given explicit written withholding period instructions, and the veterinarian should be very confident that these instructions will be faithfully followed. Where a long withholding period is provided, to ensure no residues will remain, this period should also be satisfactory as an export slaughter interval.
- the drug has been approved for use in at least one major food-producing species (for other than single animals).

Important! Some form of regulatory action may still be considered by state/territory authorities when an illegal residue occurs even if a veterinarian has followed these precautions. As indicated above, when unregistered (veterinary) chemicals are supplied, or registered chemicals are used 'off-label', the veterinarian is legally responsible if the withholding period specified on the label supplied by the veterinarian proves to be inadequate.

While veterinarians are not usually held responsible by authorities controlling residues detected in competition animals, they should understand that the livelihood of a client can be affected if such residues are detected.

The veterinarian also assumes full responsibility for complying with the conditions of use of experimental drugs or those sold under APVMA permits.

It is imperative that the veterinarian adheres to the PAD checklist criteria when using or supplying these drugs and does not on-sell these drugs to any person except the client who is the owner or custodian of the recipient animal. These drugs must not be repackaged or relabelled from the manufacturer's specifications;

however the dispensing veterinarian should affix a dispensing label as described for Schedule 4 drugs. All permit conditions must be followed.

['Off-label' use of non-restricted medications in food producing animals by owners, eg. drenches used contrary to label directions, is illegal and should be actively discouraged.]

22.6 Dispensing

Dispensing is the act of making drugs ready for supply to a client, and the sale or giving of those drugs to the client. It includes the acts of labelling and recording.

A registered veterinarian may dispense a Schedule 4 drug for an animal under his or her care, but cannot delegate this activity to a veterinary nurse, receptionist or other person except in some circumstances (see sections 13, 25 and 28). The PAD checklist criteria must be satisfied.

[Note that in Western Australia, a veterinarian's prescription may only be filled by a pharmaceutical chemist or an authorised person who holds a valid Stock Feed Manufacturers Permit.]

When dispensing a Schedule 4 drug, the veterinarian must attach a label to the container that states:

- name of owner or custodian of the animal(s);
- name or species of the animal;
- name (including business name), address and telephone number of the veterinarian;
- name of the drug;
- the words "*KEEP OUT OF REACH OF CHILDREN*" in capital letters; and "*FOR ANIMAL TREATMENT ONLY*";
- directions for use including safe handling instructions.

Additional requirements apply in each state/territory, especially for food-producing animals, and veterinarians are advised to contact their local health department for details. Note that the treatment of a single food producing animal poses a significant risk in terms of potential residue problems.

For treatments for food producing animals the label and/or advice note (if the information is too voluminous to put on the label) should provide the client with all other essential information, including re-treatment intervals (if any), route of administration, withholding periods (meat, milk, honey, eggs etc as appropriate), export slaughter interval and safe handling instructions. These are usually only required if not already appearing on the label or where they are varied by the veterinarian. Veterinarians are strongly advised to contact their local agriculture/primary industries department for regular updates.

When a veterinarian administers medication to livestock, the owner or representative must be provided with written advice regarding:

- name of the product used;
- date of treatment;
- identification or description of livestock treated;

- appropriate withholding period/s (meat, milk, eggs etc as appropriate), and export slaughter intervals;

[This information should also be provided for an unregistered product (as permitted in a particular jurisdiction) or a product to be used 'off-label'.]

The label or advice note must be handed to the owner or representative of the owner at the time of treatment; or if neither the owner nor representative is in attendance, should be left in a safe and conspicuous place at the premises where the treatment has been administered. It is advisable to check later that the advice note has been received.

If a veterinarian is prescribing or authorising 'off-label' use (but not using or supplying the chemical) or is providing an authorisation for adding a drug to stock feed, an appropriate advice note, such as the *Order for Medicated Feed* (Appendix 10), containing all the necessary details above, must be provided – see section 25.

Veterinarians cannot use, prescribe, authorise or supply any veterinary chemical for use contrary to a restraint statement (except for single animals – see below). Label restraints appear under a heading of “*Restraint/s*” and are usually worded “*DO NOT...*” or “*...MUST...*” or “*...ONLY...*”. In the Northern Territory, Queensland and Victoria all statements worded as restraints, whether under the heading or not, must be complied with in the same way. In South Australia individual product restraint statements are included in State regulations. In Victoria a specific Order covers use of streptomycin in export stock.

The use of unregistered products on companion animals, and supply of unregistered products for companion animals, are less restricted – see section 22.5.

In general, based on agreed national principles for controls over the use of veterinary chemicals, veterinarians may treat a single food-producing animal with an unregistered product, or supply a quantity of the product sufficient to treat only a single animal. Full written instructions, as for advice notes above, must be supplied.

Use of lay assistants

In some circumstances (intensive production industries, single-person practices, etc.) it might be necessary for a veterinarian to employ an assistant to help dispense drugs, for example in applying labels, packing for dispatch or physically handling large amounts of a chemical. This must only happen under the direct supervision of the veterinarian, that is they should be in the same room or in the immediate vicinity. Also, the veterinarian must ensure that any person working in this capacity is fully trained and competent.

On occasions it might be necessary to send drugs by post or courier. The labelling, packaging, addressing and dispatch are an integral part of the dispensing process and also should be closely supervised by the veterinarian. Wherever possible, receipt of the drugs should be confirmed and recorded.

22.7 Records

An accurate record of scheduled drugs, or unregistered chemicals, administered or supplied must be maintained (and kept for 2-3 years, depending on the jurisdiction). The normal veterinary medical records are a suitable form of record for this purpose.

Similar records must be kept of all 'off-label' prescriptions, authorisations and medicated feed orders issued – see sections 22.5, 25 and 28.

The records must be kept in sufficient detail to show the name of the drug, amount prescribed, authorised or dispensed, dose rate, length of course dispensed and, importantly, to indicate the grounds on which the decision was made that there was a therapeutic need for the product. There may be additional requirements in each jurisdiction. A note should be made indicating the PAD checklist has been used, particularly in cases where prescribing, authorising or dispensing has occurred in the absence of immediate clinical examination.

22.8 Advertising

Advertising of Schedule 4 drugs is not permitted, other than in professional publications. This is restricted under Commonwealth and state/territory health legislation (except in NSW where it is controlled under the Stock Medicines Act 1989). Changes to the controlling body have been recommended and in future this may be regulated by other legislation.

23 Schedule 8 drugs

Examples of Schedule 8 drugs are fentanyl, oxycodone, morphine, pethidine, pentazocine, buprenorphine, and butorphanol. [Ketamine is expected to be added to the Schedule 8 list during 2005.]

23.1 Storage and handling

In addition to the conditions outlined for Schedule 4 drugs, the following requirements must be adhered to:

- Schedule 8 drugs must be stored in a locked cabinet. Details of the cabinet specifications can be obtained from State and Territory health departments. If transport of the drug is necessary, a locked receptacle is required. Storage facilities must be secured to prevent access by unauthorised persons at all times. Staff of a practice, who are not registered veterinarians, are not 'authorised persons' under the drugs and poisons legislation and should not have access to the contents of this cabinet.
- Schedule 8 drugs must not be wilfully destroyed unless in the presence of a person authorised under the drugs and poisons legislation, and the details of destruction (name, strength, quantity of drugs destroyed, method and place of destruction) are recorded in the Schedule 8 drug record which is to be available for inspection by any authorised officer of the state/territory health department.

23.2 Prescribing and dispensing

Dispensing or prescription of Schedule 8 drugs should be done only in conjunction with a fully-documented clinical examination on each occasion.

The amount of Schedule 8 drugs dispensed or prescribed should be sufficient only for the immediate clinical requirement. If a circumstance arises where the veterinarian considers it is possible that the animal may require further supply for the condition, eg. colic in a horse, strong consideration should be given to arranging to re-visit the animal or have the animal brought to a facility for monitoring and medication.

It should be noted that the poisons classification of ketamine has recently been reviewed and is being changed to Schedule 8 in all jurisdictions during 2005. There is no legitimate therapeutic reason for dispensing ketamine in any quantity to any person.

23.3 Records

A separate record book, *Dangerous Drugs Book* or *Drugs of Addiction Register*, must be kept which records all transactions and uses and shows the accurate balance. The name of the veterinarian carrying out each transaction must be clearly recorded. The record must be in a form that cannot be altered, obliterated, deleted or removed without detection. The person carrying out each transaction must be an authorised person under the drugs and poisons legislation and sign the entry with their usual signature.

In addition detailed clinical records should be kept, as described for Schedule 4 drugs above.

24 Other restricted drugs

There are differences between jurisdictions in regard to other controls imposed for specific hazardous drugs and poisons. In most jurisdictions, injectable anabolic steroids are specifically restricted from supply to clients. In Victoria ketamine and anabolic/androgenic steroids are presently classified in a special Schedule 11. The effect of these is to provide for a greater range of law enforcement tools to be used in investigating their misuse, and to provide penalties appropriate to trafficking offences. Severe penalties apply to the misuse or unlawful supply of anabolic steroids and Schedule 11 substances.

Storage, use, dispensing and recording of other scheduled drugs

Generally these drugs may be stored in normal Schedule 4 storage facilities, but they may also be stored in a facility formerly reserved solely for the storage of Schedule 8 drugs.

In most jurisdictions there is no compulsory specific recording of such drug use or supply except for Schedule 4 'D' drugs such as anabolic steroids or the amphetamines. The use, dispensing and recording of these drugs should be recorded in the normal clinical records in the same manner as for other Schedule 4 drugs.

However all records should be able to be easily retrieved for auditing purposes and their flagging in computerised record systems is strongly recommended. Where retrieval from client records would prove difficult the use of a register is recommended. Labelling must also comply with the usual requirements.

For anabolic or androgenic steroids, it is particularly important for the veterinarian to satisfy the criteria of the PAD checklist, and to record its use. In NSW, steroids (other than testosterone for sheep) may not legally be supplied by veterinarians for use by clients under any circumstance.

It should be noted that the poisons classification of ketamine is now being changed to Schedule 8, in all jurisdictions.

Important! Dispensing of restricted drugs in large amounts is likely to attract the attention of health authorities and/or the police, and veterinary practitioners should be prepared for their records to be closely examined. Veterinarians are warned that laxity in this area would not only be considered as unprofessional conduct of a serious nature, but could also expose individuals to allegations of drug trafficking offences, which carry severe penalties under state/territory law.

25 Intensive livestock industries

Veterinarians prescribing, authorising or dispensing drugs for use in stock feeds etc. must be familiar with the relevant legislation. The prescribing veterinarian may be held responsible for any residues found in animal products as a result of any inappropriate advice.

Veterinarians supplying drugs to the pig, poultry, dairy, feedlot and aquaculture industries should adhere to the PAD checklist criteria – see section 5.

Where a licensed feed mill or premix supplier purchases and stores scheduled drugs (or stores drugs on behalf of a veterinarian), those drugs can only be incorporated in an animal feed with the authorisation of the veterinarian responsible for the stock for which that medicated feed is intended. While such authorisation initially might be a verbal direction, the veterinarian must confirm it in writing as soon as feasible, eg by providing a completed *Order for Medicated Feed* (Appendix 10).

In an emergency situation, where the veterinarian is geographically distant from the animal premises, it is acceptable for a competent, trained serviceman ('proper responsible agent' - see Section 28) to initiate medication on the verbal authority of the veterinarian. In such cases, it is essential that the tentative diagnosis and veterinarian's instructions are fully documented, and that the veterinarian takes personal responsibility for the clinical management of the animals as early as possible.

Registered veterinarians who are employed by companies not owned by veterinarians must not allow commercial pressures from non-veterinary business owners to compromise their professional integrity regarding the possession, supply

or use of drugs, and should comply with all the relevant requirements set out in these guidelines.

Special Interest Groups within the AVA, such as the Australian Association of Pig Veterinarians, the Australian Veterinary Poultry Association and Australian Association of Cattle Veterinarians, have produced codes of practice for the use of antibiotics in the relevant industry – see Appendices 2-6. These codes, which detail the responsibilities of veterinarians in the ordering, purchase, supply and use of restricted drugs in the industry, serve as useful guides to practitioners in these industries.

26 Horses and greyhounds

The dispensing of drugs by veterinarians for competing animals (horses and greyhounds) should be undertaken with care to ensure that the requirements of the relevant controlling authorities, that animals compete 'drug free', are met. This extends to all forms of competition, including eventing and dressage.

Under most rules of racing, registered trainers must not have Schedule 4 drugs in their possession unless these have been lawfully dispensed by a registered veterinarian. This places an additional obligation on veterinarians to ensure that any drugs dispensed for racing animals are clearly and properly labelled, and that quantities supplied are limited to that required to meet the immediate therapeutic need. Checks of drugs held at racing stables and kennels are regularly undertaken by racing authorities.

The label supplied with Schedule 4 veterinary chemicals dispensed for the treatment of competing animals should contain the normal S4 label information (as in section 22.6) and in addition:

- the horse's/greyhound's name or an accurate description of the animal to be treated, and
- a suitable withholding period prior to competing, as recommended by the relevant authority.

See updated information at

<http://www.racingnsw.com.au/page.asp?parm=vet.main>

27 Practices owned by non-veterinarians

In some jurisdictions it is possible for an entity, rather than a registered veterinarian, to own a veterinary practice. In this case a nominated registered veterinarian employed by the business is required to purchase and supply any restricted drugs. This registered veterinarian is the 'responsible person' and is answerable to the regulatory authority for any breaches of professional conduct in relation to the procurement, storage, use or supply of restricted drugs, and also must comply with all relevant laws in relation to drug use, supply, advertising etc.

Registered veterinarians employed in practices not owned by registered veterinarians must not allow commercial pressures from non-veterinary business owners to compromise their professional integrity regarding the possession, supply or use of drugs, and should comply with all the relevant requirements set out in these guidelines.

28 Supply to persons other than the animal owner

The supply of drugs to any person who is not the owner or responsible agent for the animal is not permitted under drugs and poisons legislation. Accordingly, supply of drugs to a third party where the veterinarian has not personally established therapeutic need for the animal(s) intended to receive the treatment could be considered wholesaling. The veterinarian who supplies drugs in such a manner is abrogating his or her responsibility to establish and record therapeutic need, to control the dose and frequency of use of the drug, to provide follow-up and after-care and to ensure correct use of the drug and understanding of its use, and any contraindications, by the end user.

Supply to a person who is a 'proper responsible agent' for an animal or herd is acceptable provided the standards of the PAD checklist are applied. Examples of this type of situation would be dispensing to a farm manager, racehorse trainer, stud manager, intensive industry serviceman or boarding kennel proprietor for the treatment of an animal(s) under the care of the registered veterinarian. There should be a formal agreement between the owner and the responsible agent. This does not diminish the duty of the veterinarian to be responsible for the diagnosis and establishment of the therapeutic need prior to dispensing.

A special situation may exist for livestock consignments, where an accredited stockman or groom can be a 'proper responsible agent'. In this situation, appropriate drugs can be dispensed as a precautionary measure. For shipments by sea, the type and quantity of drugs should be consistent with ASEL guidelines – see section 13. Where ship-to-shore communications permit, such drugs should only be administered after consultation with the dispensing veterinarian.

29 Tourists and other 'one-off' clients

It is common for non-local people to request that drugs be supplied for their animal because they are travelling and have either left the animal's drugs at home or run out of their supply. Supply of a small amount of the drug – up to three days' supply – generally is acceptable in an emergency situation. A dispensing fee may be charged.

Whenever possible, the veterinarian should contact the regular veterinary provider to obtain relevant history of the animal's medical condition and drug use. In most cases, it will also be necessary to clinically examine the animal. The combination of these two procedures will fulfil the requirement to establish therapeutic need, and create a *bona fide* relationship.

In some circumstances and for particular treatments, eg heart medication, it might be appropriate to dispense a larger quantity of the drug. This should only be done if the animal's regular veterinarian is contacted to confirm the treatment regimen.

In each of these situations it is essential that full clinical records be kept. It is advisable to use, and record the use of, the PAD checklist. A suggested notice for waiting rooms is at Appendix 14.

30 Specialists

A specialist is a registered veterinarian who holds endorsement as a veterinary specialist with their registration body. Specialists may function as primary access veterinarians but they also provide a vital service to referring veterinarians. The specialist status of this service implies increased standards not only in animal care but also in the specialist's relationship with other veterinarians.

When a case is referred to a specialist, the care of that animal becomes the responsibility of the specialist, including the treatment of a concurrent condition which may affect recovery from the initial condition. In the interests of the animal's welfare the specialist has a responsibility to manage any significant clinical problems. When those issues are addressed, the animal is handed back to the referring veterinarian, who has the responsibility to maintain the medication and treatments advised by the specialist. After-care of the animal may or may not be carried out by the specialist or referring veterinarian, depending on the circumstances. Veterinary specialists have particular responsibility to communicate to the referring veterinarian details of any treatments that have been administered.

Specialists must adhere to the PAD checklist criteria and, when acting in a referral capacity, should:

- determine, in consultation with the client and referring veterinarian, any current medications being used to treat the animal; and
- work with the referring veterinarian to ensure continuity of treatment and after-care, including any necessary further drug treatment.

31 Referral veterinarians

A referral veterinarian is any registered veterinarian who accepts referrals from other practitioners, or who provides particular services in different locations, to clients who are primarily the clients of another veterinarian.

Any drugs used or supplied by referral veterinarians should be confined to the limits of the type of work for which they are engaged.

When working as a referral veterinarian, the veterinarian should make every endeavour to work with the client's regular veterinary provider. This can work to mutual advantage if medications related to the consultancy work are to be used or supplied at times when the referral veterinarian is not in the immediate locality. The client's regular veterinarian usually will be involved in the procedures necessary for setting up the referral arrangement and also in the supply of the required drugs under the PAD checklist criteria.

The client's regular veterinary practitioner should be given access to any clinical records necessary for their knowledge of the disease or drug status of the animal or herd. This is best done by direct contact between the referral veterinarian and the regular provider (with the knowledge of the client), but could also be accomplished by ensuring that the client has copies of all relevant records which should be available to his regular provider as necessary.

It would not be in the animal's best interests for veterinarians to allow a situation to develop where business competition superseded the need to inform a client's regular veterinary provider of the details of any drugs being used on the animal or herd for which he or she had usual responsibility.

Referral veterinarians must adhere to the PAD checklist criteria and, when acting in a referral capacity, should:

- not supply, prescribe or dispense drugs other than for the treatment of the condition for which the animal has been referred (and any significant intercurrent condition) ; and
- work with the referring veterinarian to ensure continuity of treatment and after-care, including any necessary further drug treatment.

32 Relevant legislation

Commonwealth

APVMA legislation http://www.apvma.gov.au/about_us/legislat.shtml

APVMA Adverse Experience Reporting Program

<http://www.apvma.gov.au/qa/aerp.shtml>

Therapeutic Goods Administration <http://www.tga.gov.au/legis/index.htm>

Australian Capital Territory

<http://www.legislation.act.gov.au/>

Poisons and Drugs Regulations 1993

Poisons Act 1933

Poisons (Restricted Substances) Declaration 2000

Poisons and Drugs Act 1978

Animal Welfare Act 1992

Dangerous Substances Act 2004

Environment Protection Act 1997

Veterinary Surgeons Act 1994

New South Wales

<http://www.legislation.nsw.gov.au/maintop/search/inforce>

Agricultural and Veterinary Chemicals (New South Wales) Act 1994

Animal Research Act 1985

Poisons and Therapeutic Goods Act 1966

Poisons and Therapeutic Goods Regulation 2002

Prevention of Cruelty to Animals Act 1979

Stock Medicines Act 1989

Stock Medicines Regulation 1995 [to be replaced during 2005]

Pesticides Act 1999

Veterinary Practice Act 2003 [to be implemented with new Regulations in 2005]

Veterinary Surgeons Act 1986 [to be replaced during 2005]

Veterinary Surgeons Regulation 1995 [to be replaced during 2005]

Northern Territory

<http://notes.nt.gov.au/dcm/legislat/legislat.nsf?OpenDatabase>

Dangerous Goods Act 1996
Poisons and Dangerous Drugs Regulations
Poisons and Dangerous Drugs Act
Animal Welfare Act
Stock (Control of Hormonal Growth Promotants) Act
Veterinarians Regulations
Veterinarians Act
Agricultural and Veterinary Chemicals (Northern Territory) Act

Queensland

<http://www.legislation.qld.gov.au/Legislation.htm>

Agricultural and Veterinary Chemicals (Queensland) Act 1994
Health (Drugs and Poisons) Regulation 1996
Chemical Usage (Agricultural and Veterinary) Control Act 1988, Regulation 1999
Veterinary Surgeons Act 1936, Regulation 2002
Animal Care and Protection Act 2001, Regulation 2002

South Australia

http://www.parliament.sa.gov.au/leg/5_legislation.shtm

Drugs Act 1908
Agricultural and Veterinary Products (Control of Use) Act 2002
Agricultural and Veterinary Chemicals (South Australia) Act 1994
Controlled Substances Act 1984
Veterinary Practice Act 2003
Veterinary Surgeons Act 1985

Tasmania

<http://www.thelaw.tas.gov.au/advSearch/index.w3p;msg=>

Agricultural and Veterinary Chemicals (Control of Use) Regulations 1996
Animal Welfare Regulations 1993
Misuse of Drugs Act 2001
Poisons Act 1971
Poisons Regulations 2002
Veterinary Surgeons Act 1987, Regulations 1988

Victoria

http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf?OpenDatabase

Agricultural and Veterinary Chemicals (Control of Use) Act 1992, Regulations 1996
Agricultural and Veterinary Chemicals (Victoria) Act 1994
Drugs, Poisons and Controlled Substances Act 1981, Regulations 1995
Veterinary Practice Act 1997
Prevention of Cruelty to Animals Act 1986

Western Australia

<http://www.slp.wa.gov.au/statutes/swans.nsf>

Poisons Act 1964, Regulations 1965

Agricultural and Veterinary Chemicals (Western Australia) Regulations 1995

Veterinary Chemicals Control and Animal Feeding Stuffs Act 1976, Regulations 1998

Veterinary Surgeons Act 1960, Regulations 1979

33 Useful links

Australian Pesticides and Veterinary Medicines Authority

<http://www.apvma.gov.au/>

Therapeutic Goods Administration <http://www.tga.gov.au/>

National Drugs and Poisons Schedule Committee <http://www.tga.gov.au/ndpsc/>

Australian Capital Territory

ACT Health <http://www.health.act.gov.au/c/health>

Domestic Animal Services <http://www.domesticanimals.act.gov.au/>

ACT Veterinary Surgeons' Board

<http://www.health.act.gov.au/c/health?a=da&did=10033300>

New South Wales

Department of Primary Industries <http://www.agric.nsw.gov.au/reader/nsw-agriculture>

NSW Health <http://www.health.nsw.gov.au/>

NSW Board of Veterinary Surgeons <http://www.vsb.nsw.gov.au/>

Northern Territory

Department of Primary Industries and Fisheries

<http://www.atns.net.au/biogs/A001490b.htm>

Department of Health and Community Services <http://www.health.nt.gov.au/>

Queensland

Department of Primary Industries and Fisheries

<http://www.dpi.qld.gov.au/home/default.html>

Queensland Health <http://www.health.qld.gov.au/>

Veterinary Surgeons' Board of Queensland <http://vsb.qld.gov.au/>

South Australia

Department of Primary Industries and Resources

<http://www.pir.sa.gov.au/index.shtml>

Department of Health <http://www.health.sa.gov.au/>

Veterinary Surgeons' Board of South Australia <http://www.vbsa.org.au/>

Tasmania

Department of Primary Industries, Water and Environment

<http://www.dpiwe.tas.gov.au/inter.nsf/Home/1?Open>

Department of Health and Human Services

<http://www.dhhs.tas.gov.au/index.php3>

Veterinary Board of Tasmania

<http://www.dpiwe.tas.gov.au/inter.nsf/ThemeNodes/EGIL-5D78W3?open>

Victoria

Department of Primary Industries <http://www.dpi.vic.gov.au/chemicalstandards>

Department of Sustainability and Environment

<http://www.dse.vic.gov.au/dse/index.htm>

Department of Human Services <http://hnp.dhs.vic.gov.au/wps/portal>

Veterinary Practitioners' Registration Board <http://www.vetboard.vic.gov.au/>

Western Australia

Department of Agriculture

http://www.agric.wa.gov.au/servlet/page?_pageid=449&_dad=portal30&_schema=PORTAL30

Department of Health <http://www.health.wa.gov.au/>

Veterinary Surgeons' Board of WA <http://www.vetsurgeonsboardwa.au.com/>

APPENDIX 1 Prudent use of antibiotics – Global basic principles

[A paper co-sponsored by the World Veterinary Association, International Federation of Agricultural Producers and Confederation Mondiale de l'Industrie De La Sante Animale, 1999.]

This paper presents a set of principles governing the prudent use of antibiotics in animals, elaborated jointly by the international representative organisations of veterinarians, farmers, and the pharmaceutical industry. The following recommendations focus on the use and not on regulatory measures such as licensing and controls.

Note: For convenience the word 'antibiotic' is used throughout this document; it is intended to convey all antimicrobial products administered orally or parenterally to animals, i.e. antibiotics (produced by fermentation of live micro-organisms) but also chemically-synthesised compounds with antibiotic activity such as sulphonamides and quinolones; it does not include disinfectants.

1 Antibiotics are health management tools that are licensed to be used to enhance good husbandry practices for the purpose of:

- **disease prevention**
- **disease treatment**
- **production enhancement.**

It is a fact that certain antibiotics may be used in food animals for performance enhancement, which leads to benefits in terms of animal welfare, reduction of environmental waste and supply of economical high quality sources of protein. Future conditions of use of antibiotics for this indication is pending the outcome of on-going investigations and international meetings.

Antibiotics are a complement to good husbandry practices and should never be used to compensate for or mask bad farm and veterinary practices.

2 Codes of practice, quality assurance programs, flock health surveillance programs and education programs should promote the responsible and prudent use of antibiotics.

3 Antibiotics shall be used under the supervision of a veterinarian.

Regular, close veterinary involvement is essential for informed advice concerning the use of antibiotics. Regardless of the distribution system available, the use of antibiotics should be subject to appropriate professional advice, including by a veterinarian.

4 Therapeutic antibiotics should be used when it is known or suspected that an infectious agent is present which will be susceptible to therapy. It is the responsibility of the veterinarian to choose the antibiotic product, based on his/her informed professional judgment balancing the risks and benefits for humans and animals.

The veterinarian shall have due regard to the public health risks of using veterinary medicines. Specifically for antibiotics, the veterinarian shall have due consideration for the potential for decreased antibiotic susceptibility in zoonotic bacteria and target pathogens in animals, and for the antibiotic residues of toxicological and microbiological significance. At the same time, benefits such as promoting the health and welfare of animals, assuring safe, wholesome and affordable food from healthy animals, while reducing human exposure to bacteria of animal origin shall be taken into account.

Whenever bacteria are exposed to antibiotics, there will probably be some degree of selection for resistant populations. Therefore, it is vital for prudent use to limit therapeutic antibiotic use to those situations where they are warranted.

5 *When antibiotics need to be used for therapy, bacteriological diagnosis with sensitivity testing should, whenever possible, be part of the informed professional clinical judgment.*

When treating a disease, the sensitivity of the causal organism should ideally be ascertained before therapy is started. In disease outbreaks involving high mortality or where there are signs of rapid spread of disease among contact animals, treatment may be started on the basis of clinical diagnosis. Even so, the sensitivity of the suspected causal organism should, where possible, be determined so that if treatment fails it can be changed in the light of the results of sensitivity testing. Antibiotic sensitivity trends should be monitored over time, and such monitoring used to guide clinical judgment on antibiotic usage.

6 *Label instructions should be carefully followed and due attention paid to species and disease indications and contra-indications, dosage regimen, withdrawal periods, and storage instructions. 'Off-label' use of antibiotics should be exceptional and always be under the professional responsibility of a veterinarian.*

'Off-label' use should be carefully justified, for instance as part of the written prescription. Where legal provisions exist, they should serve as a basis for guiding the conditions of 'off-label' use.

7 *Antibiotics used for therapy should be used for as long as needed, over as short a dosage period as possible and at the appropriate dosage regimen.*

Dosage regimen: it is essential to administer the antibiotic in accordance with the recommended dosage regimen. This will minimise therapy failures, exploit fully the efficacy potential of the product, and comply with the regulated withdrawal times.

Each class of antibiotic has its own unique pharmacodynamic properties which are expressed fully when the recommended dosage regimen is applied.

As long as necessary: Insufficient duration of administration can lead to recrudescence of the infection. This may lead to increased likelihood of selecting microorganisms with reduced sensitivity.

As short as possible: Limiting the duration of use to only that required for therapeutic effect will minimise the exposure of the bacterial population to the antibiotic. The adverse effects on surviving commensal microflora are minimised and the medical impact of the remaining zoonotic organisms is minimised/reduced. Theoretically, antibiotic use should be stopped as soon as the animal's own host defence system can control the infection itself.

8 *Records should be kept of all antibiotic administrations.*

The implementation of record-keeping (ways and means, responsible professions) should be left to the national/local level. However, in order to ensure compatibility and usability of recorded data, some harmonisation of the principles and of the format is needed.

9 *Co-ordinated susceptibility surveillance should be conducted and the results be provided to the prescriber, supervising veterinarians and other relevant parties.*

Surveillance should target micro-organisms of both veterinary and public health importance. Data from diagnostic laboratories (with collection of samples from pathologic specimens) have an inherent bias towards a higher percentage of resistant strains than pre-treatment specimens. Therefore, it is encouraged to also gather data from samples collected at random from farm, slaughterhouses, or food in order to investigate the prevalence of resistance in veterinary pathogens, zoonotic pathogens and sentinel organisms.

Data should be provided to prescribers, supervising veterinarians and other relevant parties; which will allow the modification of antimicrobial usage to balance the benefits with the risks. Accessibility to the data will vary from program to program and should normally be determined beforehand.

10 *Efficacious, scientifically proven alternatives to antibiotics are needed as an important part of good husbandry practices.*

Among the research needs, it is suggested to look into the development of economical and efficacious alternatives to the use of antibiotics and to evaluate the impact that these alternatives (e.g. vaccines, probiotics, competitive exclusion principles and products, nutrition and new health technologies and strategies, including improved livestock management) might have on selection for resistance.

APPENDIX 2 Use of Veterinary Medicines in the Pig Industry

[Adapted from the Code of Practice prepared by the Australian Association of Pig Veterinarians (AAPV) in June 1989.]

Introduction

With the increased intensification in the pig industry, the role of the veterinarian is focussing more on herd health management, frequently necessitating treatment or preventive measures on a mass basis. Practices of Schedule 4 (S4) drug supply and usage in the pig industry have legal and ethical restraints which are outlined below.

Legal Obligations for Veterinarians Supplying S4 Substances

Veterinarians must fulfil the obligations imposed on them by the relevant legislation in the jurisdiction(s) in which they practise, that direct procedures to be followed in the supply of S4 restricted substances.

Any current practices which are contrary to this legislation should either be curtailed or modified to meet all requirements. Contrived arrangements between veterinarians and wholesalers that attempt to circumvent these mandatory requirements are to be avoided, since they jeopardise both the wholesaler's authority and the veterinarian's registration.

Responsibilities of the Veterinarian

Responsibilities of veterinarians supplying S4 restricted substances within the pig industry are detailed below.

Veterinary care and supervision of livestock

If a veterinarian is involved in the supply of a S4 substance, he/she must demonstrate due care and supervision of the recipient stock. This care and supervision should be real and not merely nominal.

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 prior to 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 on the farm or premises, to enable him/her to diagnose and/or prescribe for the animal or herd in question.

Areas of responsibility

In situations where a veterinarian is called on to prescribe or supply S4 substances, responsibilities additional to the legal obligations to be taken into account are the:

- care and welfare of the pigs that are the subject of the proposed drug supply and

- professional responsibilities of the veterinarian as described by the AVA Code of Professional Conduct.

The S4 drug supply chain

Veterinarians should carefully analyse the drug supply chain in which they are involved and delineate wholesale from retail activities. They should also check the bona fides of persons to be supplied.

The S4 drug supply chain between manufacturer and end user may be described as follows.

The wholesaler may purchase S4 medications direct from a manufacturer and subsequently supply to a veterinarian, a pharmacist, another licensed, authorised or permitted wholesaler, or an authorised receiver as stipulated by the relevant poisons legislation. The latter includes government departments, universities and hospitals, overseas countries and interstate distributors.

In all states, except South Australia, a wholesaler may not supply S4 substances direct to an end user, and cannot be authorised to do so by a veterinarian. Thus, in all states except SA, a licensed or authorised wholesale dealer is not permitted to dispense a prescription under any pretext. In some states (such as Queensland) under exceptional circumstances, direct supply to an end user can be directly authorised by the Director General of Health, but no other person. In SA, registered wholesalers may supply an end user directly, but only on the authorisation of a veterinarian responsible for and with a knowledge of the end user's pig herd. Authorisation in such cases can be given by telephone but must be followed by written confirmation within three days.

An approved feed miller can supply feedstuffs containing S4 substances under specified conditions, such as for and on behalf of, and on the written order of, a veterinarian.

A pharmacist may dispense S4 drugs to an end user but only on veterinary prescription, with one exception: in WA a pharmacist may supply certain S4 drugs in limited quantity (as specified in Regulation 39 Appendix H of the WA Poisons Act) in an emergency under certain specific conditions without a prescription.

Emergency supply of S4 drugs by a pharmacist is permitted in all states on the oral order of a veterinary surgeon, who must forward written confirmation by prescription within 24 hours.

The veterinarian accepts professional responsibility for the supply and use of S4 substances in the animals under his/her care. A veterinarian can possess S4 drugs only for the lawful practise of his/her profession. The veterinarian is not permitted to merchandise them, that is he/she cannot sell them without proper professional involvement in their use and can only supply them when he/she has made a diagnosis or has planned a medication program.

Before a pig veterinarian can supply S4 drugs he/she must be practising his/her profession. To do this, the following criteria must be met:

- the pig herd must be under the care and supervision of the veterinarian;
- the treatment recommended and the drugs supplied must be recorded;
- the client must be advised of the correct usage of the drugs; and

- if the drug is intended for treatment over a period of more than three days, it must be correctly labelled by the veterinarian, or by an assistant working under the veterinarian's personal supervision.

All veterinarians involved in the supply chain of S4 substances should continually update their knowledge of those individual or corporate entities who are registered as authorised or licensed veterinary wholesalers. State departments of health maintain an updated list of those wholesale dealers authorised, licensed or permitted under the relevant legislation.

Professional intervention

Veterinarians should fulfil the definition of 'professional intervention' in the supply chain of S4 substances. 'Professional intervention' can be defined as intervention between the drug wholesaler and the end user of the substance, in such a way as to ensure that the drug is necessary, appropriate and will be used correctly.

Veterinarians must not act as 'rubber stamps' for transactions between wholesalers and end users, but should instead be fully involved in the disease treatment and/or control program requiring the use of S4 drugs.

Documentation of professional intervention

The involvement of the veterinarian in the supply of S4 substances must be fully documented. Professional intervention should include the use of:

- The veterinarian's own stationery or his/her stamp on invoices, prescriptions, authorisations and orders and
- The veterinarian's recorded direction to supply.

When supply is made, the veterinarian must ensure that each pack or bottle of the S4 drug bears labelling as required by law, including the name and address of the veterinarian and the name of the owner or farm manager.

Instructions on drug usage should be given to the end user by the veterinarian with clear details of the method of administration, dose rate, withdrawal times and so on. These instructions can make reference to specific disease control literature originating from the veterinarian.

Records of the name and quantity of S4 drugs supplied, together with the name and address of the pig owner, must be kept for two years.

Supply of S4 drugs as part of a forward-planned medication program

There is no obligation for the veterinarian to own the drugs he/she is supplying or is responsible for supplying.

Supply of S4 substances to end users by a veterinarian is permissible according to a forward-planned medication program under the full professional control of the veterinarian. Use of medication in such a program must be a routine and not at the discretion of the end user.

In accordance with such a forward-planned medication program, use of S4 drugs from farm-held stocks supplied by the veterinarian (or a person designated by the veterinarian) can be undertaken in the veterinarian's absence but it must be done with the veterinarian's knowledge. This designated person can be defined as a piggery owner, manager or contract grower who can demonstrate that he/she has

received clear instructions, in writing, on the use of these S4 substances by the responsible veterinarian. Such a program must be kept under continual review by the veterinarian, whose written instructions are valid for a period of no more than six months.

In the case of a routine preventive program, the date of supply, the drug used, the farmer's name and volume of supply must be regularly recorded as required by law. Supply by the veterinarian must be accompanied by an invoice bearing the veterinarian's name, and the drugs correctly labelled and recorded.

In a disease outbreak, administration according to a forward-planned emergency medication program may be undertaken only when the veterinarian is confident the correct drug, from stocks supplied by him/her, will be used (if diagnosis is made from a distance). When prescribing in this manner, the veterinarian has no diminished responsibility for the diagnosis.

Stocks of S4 drugs on farms

The supply of S4 drugs for animal use to an end user other than by a veterinary surgeon or by a pharmacist on a veterinary prescription, is illegal. S4 drug stocks legally dispensed by a veterinarian for use on a pig farm are commonly stored in a central drug store. The storage of non-dispensed S4 drugs on farms remote from the veterinarian, eg the storage of unlabelled or unprescribed S4 drugs in a locked area with access exclusive to the veterinarian, is considered outside the spirit of the Poisons Act and a contravention of the Veterinary Surgeons Act, in that the veterinarian would have difficulty in demonstrating the maintenance of absolute control over these stocks.

In cases of emergency where S4 drugs may be urgently required, delays may occur if drugs have to be sent to the veterinarian by the wholesaler before being dispatched to the end user. However, only in SA is there legal provision for a wholesaler to despatch directly to the end user on oral, followed by written, authorisation from the veterinarian ordering the drugs.

Feed mills

Feed mills do not usually conform to the definition of a wholesaler but may be registered or authorised under state legislation as wholesalers, able to supply:

- Schedule 4 stock medicines to a veterinarian, pharmacist or another wholesaler; and
- feedstuffs containing therapeutic substances at exempt or S6 levels (for unrestricted sale), or at S4 level under certain conditions, as outlined below. The conditions of supply of restricted substances at S4 level to an end user specify that such supply must only be in a feedstuff, and must be on, and in accordance with, the full written instructions of a veterinary surgeon, and on his behalf, to the holder of such an order from a veterinarian – see Appendix 10.

The authorisation or registration of a feed mill under the relevant legislation does not permit that feed mill to supply S4 stock medicines for open retail sale with or without veterinary authority. Thus feed mills may not, under any circumstances, supply S4 substances to the public other than when incorporated in feed, and then only as described above.

Where a person who mixes their own feed requires S4 medication for their herd, it must be acquired from a veterinarian, a pharmacist (on a veterinary prescription), or from a feed mill as a feed concentrate (in accordance with detailed written instructions from a veterinarian). The concentrate may contain a therapeutic substance at such a level that it can be further mixed to produce medicated feed containing that drug at a specified lower therapeutic level.

There is no restriction on the supply of premixes or concentrates at levels not exceeding those set out in Schedule 6. Such premixes may be in the form of registered stock medicines or made to order by a feed mill.

The veterinarian (including those in the employ of a feed mill) must show professional intervention in the supply chain of the drug to the end user via the feed mill. In effect, the feed mill acts as an agent for the veterinarian by acting on their order or authorisation in a similar manner as a pharmacist acts in filling a prescription for a veterinarian.

Veterinarians Employed by a Company

It is recognised that companies may be directly involved with the pig industry, either by direct ownership of livestock or manufacture of S4 substances likely to be used within the industry, or both. Such companies may employ veterinarians whose responsibility may be either the health care of company-owned livestock or the provision of technical expertise in the use of S4 substances in pigs.

Veterinarians employed in such companies in whatever capacity must meet their personal obligations under the relevant State/Territory legislation regarding the use of restricted substances and their own professional activity.

Veterinarians have an obligation to point out to their employer any contravention of the legislation affecting the supply or use of S4 substances and should make every endeavour to have them rectified.

The obligations and responsibilities of a veterinarian fully employed by a company, where that company is directly involved in ownership of pigs, whether or not that company also is an authorised, licensed or permitted wholesaler of S4 substances, are the same as those of other veterinarians not so employed.

The existence of a wholesale drug purchasing group within a company does not allow that company to provide retail supply to end users (including its own stock). There should be neither direct supply nor appearance of direct supply of S4 substances by the wholesale arm of a company to outside customers, franchises (unless they also hold a wholesale authority, licence or permit), the company's own piggeries or contract growers. All are end users and can be supplied only by a veterinarian, who must intervene in the supply chain of S4 drugs and demonstrate professional intervention as previously described.

When supply is made from the company's wholesale arm to a company veterinarian, obligation to record transactions must be taken over by the veterinarian at that point. Such S4 drugs supplied to the company veterinarian (or any other veterinarian) must be held physically separated from the company's wholesale drug supplies. These supplies should be kept in a locked cupboard or room accessible only to the veterinarian. The veterinarian is required by law to keep a record of those drugs subsequently supplied.

APPENDIX 3 Use of Veterinary Medicines in the Poultry Industry

[Adapted from the Australian Veterinary Poultry Association (AVPA) *Code of Practice for the Use of Antibiotics in the Poultry Industry* 2001 Edition. This Code is endorsed by the Australian Chicken Meat Federation and the Australian Egg Corporation Limited.]

1 Introduction

1.1 Organisation of the Australian poultry industry

The Australian poultry industry is structured in a way that differs significantly from that of other livestock industries. This greatly influences the provision of veterinary services and the supply of a prescription animal remedy (PAR) or a Schedule 4 medication and other antibiotics.

In the chicken meat industry, a limited number of companies own most of the production phases, including breeding and commercial flocks, and these companies also employ veterinarians. Some chicken meat companies rely on contract broiler growing and provide veterinary services as part of that contract.

In the egg layer industry, flock ownership is largely restricted to the commercial layer chicken with stock being supplied by the breeding companies, sometimes accompanied by veterinary services. Veterinary services to egg producers (and some smaller independent poultry meat producers) may either be obtained from veterinarians in private employment, government veterinarians, poultry company veterinarians or independent consultant veterinarians.

In many of these situations, the role of the veterinarian has evolved into one of flock health management, often necessitating treatment or preventative measures on a flock basis. Practices of PAR and other antibiotic supply and usage in the poultry industry have legal and ethical restraints which are outlined below.

Company or consultant veterinarians have a responsibility to ensure their actions maintain the commercial viability of the company for which they work, but this should not override their legal or ethical obligations as a veterinarian.

1.2 Background to specific guidelines

- 1.2.1 There are practices of supply of a PAR in the poultry industry that could contravene the relevant Australian Pesticides and Veterinary Medicines Authority (APVMA) or state/territory control-of-use and health legislation.
- 1.2.2 Such practices may involve the failure of a veterinarian to provide adequate 'professional intervention' in the ordering, storage, supply and use of a PAR or on withholding periods and failure to comply with requirements for 'veterinary care and supervision of recipient stock'.
- 1.2.3 In an integrated poultry company, the supply of a PAR from the wholesale or purchasing section of the company, including premix supplier and/or feed mill, to the end user (the farm manager or broiler grower) is illegal without 'professional intervention' by a veterinarian.
- 1.2.4 Veterinarians, whether in an integrated poultry company or in private practice, have legal obligations under relevant legislation to provide

'professional intervention' in the supply of a PAR to stock 'under their care and supervision'.

- 1.2.5 Veterinarians must be familiar with Commonwealth and state legislation, as it applies to their obligations as a registered veterinarian in the state(s) in which they practice, relating to the purchase, storage, supply and use of a PAR.
- 1.2.6 The use of antibiotics is under increasing scrutiny, particularly in food-producing animals, because of the possibility of the occurrence of human health hazards due to antibiotic residues, development of antibiotic-resistant bacteria or resistance genes in food. Veterinarians are the trained professionals who are expected to oversee the prudent use of antibiotics in birds.

2 Responsibilities of the veterinarian in the supply of a PAR antibiotic within the poultry industry

The AVA has developed *Guidelines for Prescribing, Authorising and Dispensing Veterinary Medicines*. Some relevant points of these policies are included in the following sections.

2.1 Professional intervention

- 2.1.1 Veterinarians should fulfil the definition of 'professional intervention' in the supply chain of PAR medications. 'Professional intervention' can be defined as intervention by a registered veterinarian between the drug wholesaler, premix supplier or feed mill and the end user of the substance, in such a way as to ensure that the drug is necessary, appropriate and will be used (and withheld) correctly.
- 2.1.2 Veterinarians must keep a record of the drugs held in their possession in a secured area. The date of supply, the drug used, the farmer's name and volume of supply must be recorded and authorised.
- 2.1.3 When supply is undertaken by the veterinarian, each container of the PAR must bear labelling as required by law, including the name and address of the veterinarian and the name of the client. It is desirable that the PAR be in the labelled container in which it was purchased.
- 2.1.4 Written instructions as to drug use must be given to the end user by the veterinarian, with clear details of method of administration, dose rate, frequency and duration of treatment, precautions and withholding period; batch number and expiry information are desirable. These instructions can be part of specific disease control literature developed by the poultry company and delivered with the PAR medication by the serviceman undertaking dose calculations or physically administering the PAR.

2.2 Veterinary care and supervision of recipient stock

- 2.2.1 The veterinarian must not only be involved in the supply of a PAR, but must also demonstrate due care and supervision of the recipient flock. This care and supervision should be real and not merely nominal. When veterinary board investigations are undertaken because of alleged improper PAR supply, evidence will be required that the birds or flocks supplied with the PAR are under the care of the veterinarian being investigated.

- 2.2.2 When given the responsibility for the health of the flock in question by the agent or owner, the veterinarian demonstrates care and supervision by at least either:-
- having seen the flock for the purpose of diagnosis or prescription immediately prior to supply; or
 - having visited the farm or other premises on which the flock is kept sufficiently often and recently enough and from personal knowledge, inspection, records and communications to have acquired an accurate status of the current health status of the flock, to enable a diagnosis requiring a PAR to be made.
- 2.2.3 Supply in the physical absence of a veterinarian can only be done by an assistant when the veterinarian is involved and is confident by consultation that the correct drug and dose will be used. In such circumstances, the veterinarian's responsibility remains undiminished. Records must be maintained and the supply must be accompanied by written advice bearing the veterinarian's name.
- 2.2.4 When dealing with stock not owned by their employer, veterinary surgeons must practice in their own name. Company veterinarians must order the PAR medications they are prescribing and supplying or are responsible for supplying in their own name, even though the company pays for the medications. The veterinarian must always assume personal responsibility for control of PAR medications.
- 2.2.5 Veterinarians have an obligation to point out to their employer any activities in contravention of the legislation affecting the supply of PAR medications, and should make every endeavour to have these activities eliminated.

2.3 Other areas of responsibility

In situations where a veterinarian is called on to prescribe or supply a PAR, responsibilities additional to the legal obligations to be taken into account include:

- the care and welfare of the poultry flock which is the subject of the proposed drug supply; and
- the professional responsibility of the veterinarian as described in the AVA Code of Professional Conduct.

2.4 The PAR medication supply chain

Veterinarians should carefully analyse the drug supply chain in which they are involved and delineate wholesale from retail activities. They should also check the *bona fides* of suppliers and persons to be supplied. Veterinarians must prescribe and/or supply only PAR (and other) medications registered by the APVMA.

The PAR medication supply chain between manufacturer and end user comprises:-

- 2.4.1 The **wholesaler** - may purchase medications directly from a manufacturer and subsequently supply to a veterinarian, a pharmacist, another licensed or authorised wholesaler, or an authorised receiver such as a feed mill or premix manufacturer. All wholesalers supplying PAR medications must be either licensed or authorised to do so. A wholesaler may not supply direct to an end user and cannot be authorised to do so by any person. Poultry

companies can maintain a wholesale drug operation independent of veterinary involvement, but must meet their obligations under state health legislation to purchase, hold, record and supply to authorised persons or companies only.

- 2.4.2 The **feed mill** – can be authorised or licensed to receive and hold PAR medications, but cannot supply feedstuffs containing PAR medications except on the written order of the veterinarian supervising the birds to be treated – see Appendix 10.
- 2.4.3 The **pharmacist** - may only dispense a PAR medication to an end user on veterinary prescription.
- 2.4.4 The **veterinarian** - accepts responsibility for the supply and use of PAR medications for the animals under their care. Veterinarians involved in the supply chain of PAR should continually update their understanding of those individuals or corporate entities that are registered as authorised veterinary wholesalers and ensure that they know that the PAR authorised are correctly registered for sale or use in food-producing animals.
- 2.4.5 The **veterinary assistant** is a responsible person nominated by a veterinarian and can administer that medication to a flock under the directions of the veterinarian. In many instances, the assistant may also be a serviceperson or farm manager. Assistants need not be veterinarians.
- 2.4.6 The **end user** is the person who actually administers the medication, usually the farm manager or broiler grower.

2.5 Supply of PAR medications within a poultry company

- 2.5.1 There is no distinction between the supply to outside customers of a poultry company or to farms on which the company's own poultry is grown. All are recognised as end users and can only be supplied by a veterinarian (company or consultant). They cannot be supplied directly by the wholesale or purchasing section of the company.
- 2.5.2 When supply is made from the wholesale or purchasing section to a company veterinarian, obligations to record transactions must be taken over by the veterinarian at that point. A veterinarian must authorise the purchase of all PAR medications.
- 2.5.3 PAR medications supplied to the company veterinarian must be held physically separated from the wholesale drug supplies of the authorised wholesale/purchasing section of the company. This can be at the same location, but must be in a lockable cupboard or room accessible only to the veterinarian or the assistant. Veterinarians are required by law to keep a record of the drugs in their possession. In the case of a routine preventative program under the control of the veterinarian, the date of supply, the drug used, the farmer name and volume of supply must be recorded and authorised and a stocktake undertaken often enough to reconcile incoming and outgoing medications.
- 2.5.4 The use of depots to hold drug stocks on farms remote from the veterinarian may be permitted if veterinarians can demonstrate they maintain absolute control over these depots. This must be done by limiting access, appointing an assistant to be responsible in the absence of the veterinarian, maintaining an inventory of stocks in and out, auditing that inventory

regularly, and ensuring that no supply occurs without the authority of the veterinarian. A similar situation must apply to a serviceperson's car. In addition, PAR medications held in a serviceperson's car should be stored out of public view in a suitable container and be limited to that which has been authorised by the veterinarian. The veterinarian remains accountable for the quantity of each PAR in the serviceperson's possession. The medications held by the serviceperson can only be obtained from a veterinarian's stock and must be correctly labelled as outlined above.

- 2.5.5 Out-of-state veterinarians supplying PAR medications must comply with 'professional intervention' and 'veterinary care and supervision of recipient stock' requirements as described above and must adhere to relevant state legislation.

2.6 Obligations of government veterinarians

All veterinarians, including government veterinarians, can only receive PAR medications from either a pharmacist following the issuing of a prescription, a veterinarian or on an order from an authorised wholesale supplier.

2.7 Feed mills/premix suppliers

- 2.7.1 Feed mills and premix suppliers may be authorised or licensed to receive and store PAR medications (as wholesalers) and must comply with the conditions attached to the licence. The feed mill/premix supplier may supply feed/premix in which antibiotics are incorporated at registered S6 or exempt levels for unrestricted sale without 'veterinary intervention'. Where the feed/premix contains PAR medications, it may only be supplied on and in accordance with the full written instructions of the veterinarian supervising the birds to be treated – see Appendix 10.

Feed mills/premix suppliers may not, under any circumstances, supply PAR medications other than incorporated in feed or premix.

- 2.7.2 Persons who mix their own feed, who require a PAR medication for their flock, must acquire the PAR from a pharmacist (on a veterinary prescription) or veterinarian or from a feed mill as a feed concentrate (in accordance with full written instructions from the veterinarian responsible for the stock to be treated). The concentrate may contain a PAR at such a level that it can be further mixed to produce medicated feed containing that drug at a specified therapeutic or prophylactic level.
- 2.7.3 The veterinarian (including those in the employ of a feed mill if they have direct supervision of birds to be treated) must comply with the requirements of 'professional intervention' and 'veterinary care and supervision of recipient stock', as given above to be involved in the supply of PAR medications to the end user. Such supply by veterinarians must be done in their own names and requires the recording of receipt and supply as would normally apply to PAR (S4) medication usage.

3 Responsibilities of the veterinarian in the supply of a non-PAR antibiotic

- 3.1 Veterinarians are not legally required to be involved in the supply and use of non-PAR medications.

- 3.2 However, veterinarians are professionally trained in the diagnosis of bacterial conditions and to understand the requirements for antibiotic use and are usually involved in the decision-making process for use of non-PAR antibiotics, including growth promotants, in the poultry industry.
- 3.3 With the increasing public debate into the use of antibiotics in food-producing animals and the possibility that human health hazards can be created via the occurrence of antibiotic-resistant bacteria or resistance genes that develop in animals, veterinarians should ensure that Prudent Use Guidelines for Antibiotics (whether PAR or non-PAR antibiotics) are understood and should encourage adherence to these guidelines – see Appendix 1.

4 'Off-label' use of antibiotics

- 4.1 'Off-label' use of both PAR and non PAR antibiotics by registered veterinarians should be confined to situations where medications used according to label instructions have been ineffective and where there is scientific evidence, including residue data, supporting the 'off-label' use pattern.
- 4.2 Control-of-use legislation relating to 'off-label' use of antibiotics currently differs between states. Veterinarians should be familiar with the requirements of the jurisdiction(s) in which they are registered to practice. However, all states/territories have agreed to 'harmonisation conditions' for control-of-use legislation. Agreed conditions include:
- only a registered veterinarian may vary the label instructions for antibiotic use;
 - off-label use in poultry flocks will be permitted only if the antibiotic is registered in another major food-producing animal species;
 - veterinarians will not be able to vary label instructions contrary to a 'label restraint' for antibiotic use in poultry, eg. *"Not to be used in poultry producing eggs for human consumption"*;
 - veterinarians must supply written instructions for use and withholding periods;
 - veterinarians may be liable if violative residues occur.

5 Prudent use guidelines for antibiotic use

Refer to Appendix 1.

APPENDIX 4 Use of Veterinary Medicines in Equine Practice

[Adapted from the Code of Practice prepared by the Australian Equine Veterinarians Association.]

Introduction

The prescribing practices of equine veterinarians are under increasing scrutiny from health authorities, sporting bodies and veterinary boards as a result of concerns that a variety of registered drugs are being obtained and used inappropriately. Veterinary anabolic steroids are a source of particular and increasing concern to public health authorities, and are considered to be widely abused.

In addition, the increasing costs and regulation surrounding registration of veterinary pharmaceuticals is tending to limit the prescribing options available to veterinarians in general and equine practitioners in particular. In the light of these pressures, it is important that the veterinary profession respects its prescribing privileges, recognises its obligations and maintains a responsible position.

These guidelines have been developed following extensive consultation with the profession, state and territory registration bodies and health departments, the APVMA, and the Commonwealth Department of Human Services and Health. This is not a legally binding document but it is intended to assist practising equine veterinarians maintain good professional and ethical standards regarding prescribing and dispensing.

Supply of a restricted pharmaceutical implies that the prescribing veterinarian has been entrusted with and has accepted the primary responsibility for the health and well-being of the patient concerned. In order to legally prescribe a Schedule 4 drug, a veterinarian must be practising as a veterinarian, this means among other things, that the animal must be under his/her care. The veterinarian's sphere of responsibility includes:

- accurate diagnosis and therapy of disease conditions;
- appropriate management and advice for adverse reactions;
- knowledge of medication regulations of equine sporting bodies;
- disposal of used needles and syringes and excess drugs;
- public health implications and drug residues;
- ensuring that medication is not likely to be diverted to illicit use; and
- ensuring that all medication is stored in a secure manner.

The implications and consequences of prescribing and dispensing should be considered for each individual case. The veterinarian should take account of the interests of the owners, lessees, insurance companies, race clubs and other third parties in addition to those of the horse and its primary carer. Notwithstanding the veterinarian's responsibility for ethical and legal drug dispensing, it is important that actions of the profession do not lead to imposition of unnecessary barriers to the legitimate use of restricted medications, by way of price or availability.

1 Dispensing requirements

Printed drug labels must include practice name and address and conform to state departments of health standards regarding format, colour, content and warnings. This includes the warning "*Keep Out of the Reach of Children*" in red on a white background.

All restricted medication must be labelled on the bottle, vial or tube, **not the carton**, with:

- owner's name;
- species ie. "horse";
- approved name of the substance and its proprietary name;
- date of prescription; and
- dosing instructions.

Excess label may be folded over in the form of a 'flag'.

It is desirable that the medication be dispensed in its original container. Alternatively, the dispensed dose must be clearly labelled with the name and concentration of the drug. Dispensing containers should be glass or plastic. Certain restricted substances may only be legally supplied in a child resistant container or a blister package (refer to state health department guidelines).

Syringes should be capped and should not be dispensed with needles attached.

Medication stored at the surgery, carried in a bag or car, or left at premises should be stored in a secure manner.

A clinical record of prescribing and dispensing should be maintained including the date and amount of drug prescribed. If the veterinarian's dosing instructions vary from the label directions the dose should be noted on the record. In the case of Schedule 8 and Schedule 4 (notably anabolic) drugs, clinical records should include directions for use.

The prescription must be personally dispensed by the attending veterinarian, by an assistant working under direct supervision, or by a registered pharmacist.

If slaughter for human consumption is a potential fate of the animal, advice should be given on the withholding period.

2 Client-veterinarian relationship

Veterinarians should only prescribe restricted drugs for horses in their care. This care must be real and not merely nominal. They must be given, and accept, responsibility for the health of horse or stable in question, including arrangements for emergency care. The veterinarian should have either seen the animal for whom the drug is prescribed, or have visited the stable or premises sufficiently often and recently enough to competently prescribe the drug in question. In remote areas, regular personal visitation may be impractical and telephone consultation must suffice. The veterinarian is obliged to ensure he/she is offering the best available service, that the horse's welfare is the foremost consideration, and that the prescribing obligations can be discharged faithfully.

Prescribing should only follow an accurate diagnosis, and should take account of the horse carer's skills, in particular their ability to administer the drug, assess the response and dispose of unused drugs, needles and containers.

The veterinarian should be aware of and advise clients about adverse reactions, residues and regulations relating to the use of medications in performance and race horses.

Where a horse comes into the occasional care of a veterinarian, for example for competition, stud, or referral, drugs dispensed should be limited to those specific to the condition for which the attending veterinarian is consulted. Repeat prescriptions and requests for other medication should be referred to the veterinarian who is usually responsible for the veterinary care of the horse.

3 Prescribing quantities and reassessment intervals for long-standing conditions and treatments

While quantities dispensed and duration of therapy remains the judgement of the attending veterinarian, that no more than two months' supply of a long term medication should be dispensed on one prescription, with up to two repeat authorisations before a reassessment is indicated. This means that a prescription should permit a maximum six month interval between visits or consultations.

4 'Off-label' use of registered medications and drugs registered for human use

Usage should be confined to situations where no suitable registered veterinary preparation is available and where there is scientific evidence supporting extra-label use. This would include credible extrapolation from scientific literature of the drug's suitability, including activity and safety at the proposed dose and route of administration.

Variations in label dosage, treatment interval and route of administration are at the veterinarian's discretion, taking note of available knowledge of efficacy and safety.

5 Extemporaneous prescriptions

A registered veterinary chemical product should be chosen where available.

If an extemporaneous preparation is offered on economic grounds, the owner should have the implications of this choice with respect to quality control and manufacturer support explained.

Where a drug is used outside established bounds of safety and efficacy, the owner or agent's informed consent should be obtained. Insurance implications (professional indemnity and bloodstock mortality) should be considered.

6 Anabolic steroids

Injectable anabolic steroids should be administered by the attending veterinarian. Repeat quantities and intervals should be noted on the clinical record.

7 Sedatives for Clipping, Shoeing, Dentistry and Breaking

Sedatives should be dispensed only for use in horses under the care of the prescribing veterinarian and in doses suitable for the immediate need. Hazards of sedation to the horse and operator should be explained.

8 Prostaglandins

Prostaglandins present particular health hazards to humans, and should be dispensed only to experienced operators, with handling precautions emphasised. State veterinary board directives on prostaglandin dispensing should be followed. Administration by veterinarians is preferred.

9 Local and general anaesthetics

There are no legitimate indications to dispense injectable local and general anaesthetics in equine practice.

10 Emergency Supplies

Reasonable quantities of an emergency drug may be prescribed in advance for experienced clients to have on hand as would be required to manage emergency cases under supervision. Suitable labelling would include:

- owner's name,
- "horse",
- date, and
- the words: "*For emergency use under supervision*".

The veterinarian should make a clinical note of directions and observations communicated by telephone. The horse carer should keep a diary record of all medication administered under supervision.

11 Pesticides

Pesticides must be sold in the original container, and used only for the label purpose, unless an APVMA permit is obtained.

12 Drugs of addiction - Schedule 8

Use of Schedule 8 drugs requires compliance with state dangerous drug laws, including maintenance of a dangerous drug register. The drug methylphenidate (*Ritalin*) has no legitimate indication in equine practice. Veterinarians should be familiar with the laws relevant to the use of S8 drugs in their state.

APPENDIX 5 Use of Veterinary Medicines in the Sheep Industry

[Prepared by the Australian Sheep Veterinary Society 2004.]

Introduction

Antimicrobial drugs are used in the sheep industry either to treat individual animals or as part of a preventive or disease control program where a significant proportion of the flock may be treated. They are used to prevent or control bacterial and protozoal diseases in a flock situation, often involving treatment of a large number of individual animals.

Veterinarians have a responsibility to develop relationships with their clients to ensure that the limited number of antimicrobials presently available in the sheep industry are used correctly and that their use is preserved and protected. In terms of intensive sheep production systems these are developing, with feed lotting now being used to finish lambs for slaughter and to hold sheep prior to export.

The sheep veterinarian is often placed in a difficult situation because of the economics of the industry. The individual animal in the flock often has a low commercial value in relation to the cost of a veterinary investigation. This has been further aggravated by the loss of the services previously provided by a regional veterinary laboratory service. This often means that the sheep owner will attempt to obtain medications for the flock without a veterinary visit or they will attempt to find alternative sources for the supply of restricted drugs, including most of the antimicrobials.

Where a veterinarian is supplying antimicrobials for the treatment or prevention of sheep diseases, there must be an established *bona fide* veterinarian-client relationship.

The veterinarian has a role to ensure that a diagnosis is established before recommending any antimicrobial treatment, that the most suitable drug is selected, that particular attention is paid to withholding periods for slaughter and for export and that appropriate records are kept of all treatments applied to sheep in the flock. The veterinarian should also ensure that appropriate management and vaccination programs are in place to reduce or eliminate the need for antimicrobial treatments eg the eradication of footrot from a flock eliminates the need for antibiotic treatments for salvage of individual animals.

1 Establishing the need for antimicrobial treatment

This requires:

- an examination of the flock or affected animal to establish an accurate diagnosis, including an assessment of the proportion of the flock that is affected and the proportion of the flock that may need treatment or an established client/animal/practitioner relationship in the case of planned disease control or eradication programs under the supervision of a registered veterinarian;
- an investigation of the reasons predisposing to the disease outbreak;

- an assessment of alternative management or husbandry procedures that could be used as an alternative to antimicrobial treatments.

2 Treatment Protocols

Antimicrobials should not be used routinely as a prophylactic after surgical procedures. An aseptic technique before and during surgery should eliminate the need for any such use.

The veterinarian should consider the following when selecting an antimicrobial for use in treating sheep:

- The likely pathogen and the potential for antimicrobial resistance. Whilst resistance is not perceived as a problem within the sheep industry (perhaps because antibiotics have not been used extensively within the industry), the possibility must be considered in recommending a treatment.
- The delay in obtaining confirmation of a suspected diagnosis from a veterinary laboratory means that in most cases, the veterinarian is obliged to recommend or apply an antimicrobial treatment on the basis of a field diagnosis.
- The effect of the environment on the efficacy of the treatment. For example, many of the antibiotic treatments for footrot or dermatophilosis are not effective if the animal is exposed to a moist environment within 24 hours of treatment. With footrot, it may require shedding sheep in a dry environment eg on grating in a shearing shed, to allow the antibiotic to achieve a significant cure rate.
- Whether the animals are to be retained on the farm or whether they are likely to enter the food chain. If the animals could be slaughtered in the short term, then the selection of the antimicrobial must consider the withholding period for meat, with particular reference to the export slaughter interval.

'Off-label' recommendations should not be made when there is a suitable product registered for the treatment of the particular condition that is already registered. Any 'off-label' recommendation must only use a product that is registered for use in food producing animals.

When using or recommending an 'off-label' treatment the availability of information on which to base a recommendation for a withholding period must be considered. The veterinarian will be held responsible for any adverse reactions that may occur as a result of an 'off-label' recommendation.

(This will include advice on the need to abide by state/territory legislation and will mention the requirements for advice on dose rates, withholding periods etc)

3 Recording information

The veterinarian should develop a recording system for use by the farmer to record all antimicrobial treatments applied to the flock or individual animals in the flock. This record system should be compatible with quality assurance systems that may be required as part of a flock accreditation scheme eg *Flockcare* or those required by meat processors or purchasers of store stock.

Where individual animals within a flock are being treated, then an individual animal identification should be applied to identify the animals that have been treated.

4 Diseases and conditions where antibiotics are likely be used in the sheep industry

- Anthrax
- Footrot
- Dermatophilosis
- Campylobacter abortion
- Coccidiosis
- Yersiniosis
- Pneumonia in feedlot and intensive systems
- Mastitis in sheep dairies
- Foot abscess
- Lactic acidosis
- Salmonellosis.

APPENDIX 6 Use of Veterinary Medicines in the Cattle Industry

[Prepared by the Australian Association of Cattle Veterinarians 2005.]

1 Introduction

The Australian cattle industry comprises three main sectors:

- Dairy industry predominantly based on pasture, with various levels of supplementation and intensification.
- Beef feedlot industry characterised by intensive production systems with high levels of supplementary feeding.
- Extensive grazing on natural or improved pastures with relatively lower stocking rates.

Each sector presents different challenges to veterinarians in the management and supply of prescription animal remedies or Schedule 4 medicines. In general there is a trend to increased intensification in each of these sectors. The role of the veterinarian is becoming more focussed on treatment or preventive measures on a herd basis, especially in the dairy and feedlot sectors. Legal and ethical considerations in the supply and usage of PAR compounds in the cattle industry are outlined below.

2 Legal obligations

Veterinarians must fulfil the obligations imposed on them by the relevant legislation in each jurisdiction in which they practise. The legislation stipulates the correct procedures to be followed when supplying PAR substances and is enforced by the department of health and veterinary registration authority in each state/territory.

Any contrived arrangements between veterinarians and wholesalers that attempt to circumvent these mandatory requirements must be avoided, as they jeopardise both the wholesaler's authority and the veterinarian's registration.

3 Responsibilities of the veterinarian

Responsibilities of veterinarians supplying PAR restricted substances within the cattle industry are detailed below.

Veterinary care and supervision of livestock

A veterinarian involved in the supply of a PAR must demonstrate due care and supervision of the recipient stock. This care and supervision should be real and not merely nominal.

When given responsibility for the health of an animal or herd by the owner or his agent, the veterinarian demonstrates care and supervision by:

- having seen the animal or herd for the purpose of diagnosis or prescription immediately prior to supply; or
- having visited the 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 animal health status on the premises, to enable him/her to diagnose and/or prescribe for that animal or herd; and

- being satisfied that farm personnel have the skill and are fully aware of the requirements imposed by a veterinary prescription to ensure that animals under the care of the veterinarian will be treated with a PAR according to the directions of the veterinarian.

Areas of responsibility

In situations where a veterinarian is called on to prescribe or supply PAR substances, responsibilities additional to the legal obligations to be taken into account are the

- care and welfare of the recipient cattle, and
- professional responsibilities of the veterinarian as described by the AVA Code of Professional Conduct.

4 The PAR supply chain

Veterinarians should carefully analyse the drug supply chain in which they are involved and delineate wholesale from retail activities. They should check that persons to be supplied have a genuine client-patient relationship with the veterinarian or the veterinary practice.

Veterinarians should only prescribe or supply PAR medications which are registered by the Australian Pesticides and Veterinary Medicine Authority (APVMA).

The PAR supply chain between manufacturer and end user may be described as follows:

- The **wholesaler** may purchase PAR medications direct from a manufacturer and subsequently supply to a veterinarian, a pharmacist, another licensed, authorised or permitted wholesaler, or an authorised receiver as stipulated by the relevant poisons legislation. All wholesalers supplying PAR medications must be either licensed or authorised to do so. A wholesaler may not supply direct to an end user and cannot be authorised to do so by any person, unless permitted by state/territory legislation.
- An **approved feed miller** can supply feedstuffs containing PAR substances under specified conditions, such as for and on behalf of, and on the written order of, a veterinarian (see Appendix 10 for recommended format).
- A **pharmacist** may dispense PAR substances to an end user only on veterinary prescription, unless permitted by state/territory legislation.
- The **veterinarian** accepts professional responsibility for the supply and use of PAR substances in the animals under their care. A veterinarian can possess PAR drugs only for lawful professional practise activities. The veterinarian is not permitted to merchandise these products, that is a S4 compound cannot be sold without proper professional involvement in its use, and can only supply the S4 when he/she has made a diagnosis or has planned a medication program.

Veterinarians involved in the supply chain of PAR compounds should continually update their database of companies and individuals which are registered as authorised veterinary wholesalers. State departments of health maintain an updated list of those wholesale dealers authorised, licensed or permitted under the

relevant legislation. Veterinarians must also ensure all PAR compounds prescribed are registered by the APVMA for sale or use in food producing animals. Before a veterinarian can supply PAR drugs he/she must be a registered in the state/territory in which the client is located. To prescribe correctly, the following criteria must be met:

- the cattle herd must be under the care and supervision of the veterinarian;
- the treatment recommended and the drugs supplied must be recorded;
- the client must be advised of the correct usage of the drugs (including relevant withholding periods and export slaughter intervals); and
- the drug intended for treatment must be correctly labelled by the veterinarian, or by an assistant working under the veterinarian's direct supervision.

5 Professional intervention

Veterinarians should fulfil the definition of 'professional intervention' in the supply chain of PAR substances. 'Professional intervention' can be defined as intervention between the drug wholesaler and the end user of the substance, in such a way as to ensure that the drug is necessary, appropriate and will be used correctly.

Veterinarians must not act as 'rubber stamps' for transactions between wholesalers and end users, but should instead be fully involved in the disease treatment and/or control program requiring the use of PAR drugs.

Documentation of professional intervention

The involvement of the veterinarian in the supply of PAR substances must be fully documented. Professional intervention should include the use of the veterinarian's

- own stationery or his/her stamp on invoices, prescriptions, authorisations and orders, and
- recorded direction to supply.

When supply is made, the veterinarian must ensure that each pack or bottle of the PAR drug bears labelling as required by law, including the name and address of the veterinarian and the name of the owner or farm manager.

Instructions on drug usage should be given to the end user by the veterinarian with clear details of the method of administration, dose rate, withholding periods and export slaughter intervals. These instructions can make reference to specific disease control literature prepared by the veterinarian.

Records of the name and quantity of PAR drugs supplied, together with the name and address of the pig owner, must be kept for two years.

6 Stocks of PAR drugs on farms

The use of depots to hold drug stocks on farms remote from the veterinarian may be permitted if veterinarians can demonstrate they maintain absolute control over these depots. This must be done by limiting access, appointing an assistant to be responsible in the absence of the veterinarian, maintaining an inventory of stocks in and out, auditing that inventory regularly, and ensuring that no supply occurs without the authority of the veterinarian.

7 Feed mills

Feed mills and premix suppliers may be authorised or licensed to receive and store PAR medications (as wholesalers) and must comply with the conditions attached to the licence.

The feed mill or premix supplier may supply feedstuffs containing Schedule 6 therapeutic substances (for unrestricted sale), or at PAR level under certain conditions, as outlined below. Where the feed/premix contains PAR medications, it may only be supplied on and in accordance with full written instructions of the veterinarian supervising the animals to be treated – see Appendix 10. Feed mills and premix suppliers may not, under any circumstances, supply PAR medications other than incorporated in stock feed or premix.

Where a person who mixes their own feed requires PAR medication for their herd, it must be acquired from a veterinarian, a pharmacist (on a veterinary prescription), or from a feed mill as a feed concentrate (in accordance with detailed written instructions from a veterinarian). The concentrate may contain a therapeutic substance at such a level that it can be further mixed to produce medicated feed containing that drug at a specified lower therapeutic level.

There is no restriction on the supply of premixes or concentrates at levels not exceeding those set out in Schedule 6. Such premixes may be in the form of registered stock medicines or made to order by a feed mill.

The veterinarian (including those in the employ of a feed mill if they have direct supervision of cattle to be treated) must comply with the requirements of 'professional intervention' and 'veterinary care and supervision of recipient stock', when supplying PAR medications to an end user. Such supply by a veterinarian must be done in their own name and requires the recording of receipt and supply as would normally apply to PAR medication usage.

8 Veterinarians employed by a company

It is recognised that companies may be directly involved with the cattle industry by direct ownership of livestock. Such companies may employ veterinarians whose responsibility may be either the health care of company-owned livestock or the provision of technical expertise in the use of PAR substances in cattle.

Veterinarians employed in such companies in whatever capacity must meet their personal obligations under the relevant state/territory legislation regarding the use of restricted substances and their own professional activity.

Veterinarians have an obligation to point out to their employer any contravention of the legislation affecting the supply or use of PAR substances and should make every endeavour to have them rectified.

The obligations and responsibilities of a veterinarian fully employed by a company, where that company is directly involved in ownership of cattle, are the same as those of other veterinarians not so employed.

PAR drugs supplied to the company veterinarian (or any other veterinarian) must be held physically separated from the company's wholesale drug supplies. These supplies should be kept in a locked cupboard or room accessible only to the

veterinarian. The veterinarian is required by law to keep a record of those drugs subsequently supplied.

9 Responsibilities of the veterinarian in the supply of non-PAR antibiotics

Veterinarians are not legally required to be involved in the supply and use of non-PAR medications.

However, veterinarians are professionally trained in the diagnosis of bacterial conditions and to understand the requirements for antibiotic use. Cattle veterinarians are often involved in the decision-making process for use of non-PAR antibiotics, including growth promotants.

There is increasing public debate about the use of antibiotics in food-producing animals and the possibility that human health hazards can be caused by the creation of antibiotic-resistant bacteria or resistance genes in animals. Therefore veterinarians should ensure that *Prudent Use Guidelines for Antibiotics* (whether PAR or non-PAR antibiotics) are understood and should encourage adherence to these guidelines (see Appendix 1).

10 'Off-label' use of antibiotics

'Off-label' use of both PAR and non PAR antibiotics by registered veterinarians should be confined to situations where medications used according to label instructions have been ineffective and where there is scientific evidence, including residue data, supporting the 'off-label' use pattern.

Control-of-use legislation relating to 'off-label' use of antibiotics currently differs between states. Veterinarians should be familiar with the requirements of the state(s) in which they are registered to practice. All states have agreed to 'harmonisation conditions' for control-of-use legislation and this process is nearing completion (February 2005).

Agreed conditions include:

- only a registered veterinarian may vary the label instructions for antibiotic use;
- off-label use in cattle herds will be permitted only if the antibiotic is registered in another major food-producing animal species;
- veterinarians will not be able to vary label instructions contrary to a 'label restraint' for antibiotic use in poultry, eg. *"Not to be used in animals likely to producer milk for human consumption"*;
- veterinarians must supply written instructions for use and withholding periods; and
- veterinarians may be liable if violative residues occur.

[In addition to these broad categories of guidelines for the use of PAR compounds in cattle, the Australian Association of Cattle Veterinarians (AACV) is developing a series of guidelines for specific situations when prescribing PAR drugs to cattle.

Guidelines to be developed include:

- *In feed medications in dairy and feedlot herds;*
- *Dry cow therapy in dairy cattle;*

- *Prevention of drug residues in bobby calves;*
- *Mass medication in cattle feedlot enterprises;*
- *Prescription and dispensing for cattle in the live animal export trade;*
- *Anti-inflammatory drug use in cattle;*
- *Prescription and dispensing for cattle involved in embryo transfer.*
- *Prescription and dispensing prostaglandins for use in cattle.]*

APPENDIX 7 Safe Use of Veterinary Medicines on Farms

[Prepared by the AVA Therapeutics Subcommittee and adopted in February 1990.]

Source of Medicines

Before registration, all agricultural chemicals and veterinary drugs are subjected to stringent assessment and approval systems that take account of the:

- efficacy and safety of the product;
- effect of the drugs and chemicals on target and non-target species and the environment;
- effect of the drugs on the health and safety of operators using them;
- effect on public health and safety from residues in food and fibre and the setting of withholding periods for meat, milk and eggs;
- security of export and domestic markets.

Therefore farmers should ensure that only approved medicines and chemicals are used.

Obtain your medicines only from your veterinary surgeon, pharmacy or reputable distributor. Sales from other sources may be illegal and the medicines may be neither safe nor effective.

Storage

Store your medicines correctly in accordance with the instructions on the label. Storage temperature is critical for some medicines, especially vaccines. Light can damage others. Make sure your medicines are stored securely, under lock and key where practicable. Keep out of the reach of children, animals and anybody not supposed to handle the medicines.

Record Keeping

Keep a record to show:

- The name, quantity and batch number of any particular medicine purchased and the date and place it was purchased.
- The total quantity of medicine used, dose rate, dates treatment started and finished and the identity of the animals (groups or individuals) on which it was used.
- Where the medicine is used in food-producing animals, the duration (in days) of the withholding period and the dates of the beginning and end of the withholding period for each individual animal or group of animals treated.

When your veterinary surgeon prescribes a medicine he/she may wish to specify the form of record to be kept. Keep the record safely for at least two years. Your veterinary surgeon may need to see it. [Refer to Appendix 11.]

Administration of Medicines

Read the label carefully before administering the medicine. It is important that the dose and method of administration are correct. In particular the route and site must be right for injections.

Check any warning statements and directions about how the medicine should not be used. In particular, check whether it can be used with any other medicines being given to the animal. Do not use the product if it is past its 'Use by' date shown on the label.

You or a reliable member of your staff should be personally responsible for the recording, safeguarding and administration of medicines and for seeing that the withholding period is observed. Your veterinary surgeon will be able to help with training in administration of medicines and injections. Untrained persons should not administer or have responsibility for medicines except under supervision.

Use medicines only on animals recommended on the label or leaflet, unless you have been directed to do otherwise by your veterinary surgeon. The result of giving a medicine to an animal for which it is not registered is unpredictable, can endanger the animal, and may leave residues. It may also be illegal.

Consult your veterinary surgeon for advice about medication for sick animals.

Withholding Periods

Be careful to observe any withholding period laid down for the particular medicine between the end of treatment and the slaughter of the animals or the taking of their eggs or milk for human consumption. If the animals are sold before the end of any withholding period, it is important that you advise the purchaser and/or auctioneer or other dealer in writing.

The identity of all treated animals must be recorded.

It is vital to avoid residues in meat or other livestock produce, so observe these precautions strictly, especially in the case of emergency slaughter.

Milk from quarters of cattle treated for mastitis must not be fed to calves or other animals to be sold for slaughter.

For further information on withholding periods contact your veterinarian, manufacturer or distributor.

Disposal of Unused Medicines or Containers (including dip washes, footbaths, etc)

Dispose of unused medicines safely according to label directions when treatment is finished. Further information may be obtained from the manufacturer or state environmental protection authority. Do not hoard partly used medicines just in case they may be useful later.

Injections

If administration of the medicine involves single or multiple injections, the following simple rules will help reduce the risks of spreading infection and avoid carcass damage:

- Sterilise all injection apparatus by boiling or as recommended by the manufacturer before use. Avoid use of strong disinfectants on apparatus.
- Maintain cleanliness at all times.
- Keep needles sharp and clean; replace frequently.

- Use needles of appropriate gauge and length. For subcutaneous administration, use the shortest needle possible, certainly not exceeding 15 mm.
- Avoid injection of animals in wet weather or under dusty conditions as far as possible.
- If you are using a syringe which has to be filled from the bottle between doses, leave one sterile needle in the bottle for filling the syringe while using another needle to inject. Remember to remove the needle when finished.
- In the case of an automatic refill syringe, if an air bleed is required to equalise pressure as the injection fluid is withdrawn, use a sterile needle for this purpose.
- Unless otherwise recommended by your veterinarian, intramuscular injections should be made into muscle tissue on the side on the side of the neck, and subcutaneous injections should be made under the skin high on the neck behind the ear. Make the injection through an area of clean, dry skin.
- All partially used containers of vaccines and other contaminated injectable products should be disposed of properly.
- Dispose of needles and syringes safely, eg in a strong, impervious container.

Note that the *CATTLECARE* quality assurance program stipulates a maximum injection volume of 10 ml at any single site; all deep intramuscular injections must be administered into the neck muscles. The requirements for other quality assurance programs should be checked.

Feed Medication

Order premixed feed or prepare medicated feed exactly in accordance with directions using registered products only. On delivery, carefully check the docket and bag labels to see whether foods contain the right medication in the right concentration. Store medicated feed separately from non-medicated feed. Only animals that require medication should be given medicated feed. Use only those medications approved for use in the animal age group.

All mixing equipment should be thoroughly cleaned after use of medications to ensure that subsequent batches are not contaminated.

Water Medication

Water in drinkers needs to be completely removed and replaced with carefully diluted medicated water, which should be the only source of water available.

Ensure that there are no residues of disinfectants in drinkers and water lines prior to the addition of diluted vaccines. It is recommended that disinfectants not be used for seven days before and one day after vaccination.

Use accurate weight and volume measures. Many drugs deteriorate rapidly when dissolved in water and the medicated water must be replaced frequently. When the medication period is completed, drinkers need to be drained and refilled with clean water.

Pesticides

Be careful when using pesticide sprays (for termites, spiders, etc.) in animal sheds or near stored feed. Residues of some pesticides may persist for many years in meat, milk, eggs and other produce.

Emergency Telephone Numbers

Keep handy a list of emergency telephone numbers:

- Poisons Information Centre,
- Local doctor,
- Local hospital,
- Your veterinary surgeon.

APPENDIX 8 Use of Cytotoxic Drugs

[Adapted from material published by the Queensland, Victorian and South Australian departments of occupational health and safety. 2005]

Introduction

The use of cytotoxic drugs is increasing in veterinary practice, primarily for the treatment of cancers in animals such as dogs, cats, birds and horses. Animal treatments present particular risks, and close attention should be paid to preventing environmental contamination by excreted drugs because contaminated excreta are not as easily managed, compared to human patients.

Workers involved with cytotoxic drugs who should be trained in the handling of cytotoxic drugs and related waste include veterinarians, veterinary nurses and staff such as animal attendants and cleaners. For ease of management, it is preferable to restrict the number of people performing tasks involving cytotoxic drugs and handling of waste.

Drug preparation

Drug preparation should be done in a clean room following standard recommended procedures and equipment – see websites below. If these facilities are not available, it is strongly recommended that a commercial cytotoxic drug admixture service be used for drug preparation.

Drugs for individual animal use must be labelled as required by the relevant jurisdiction. A childproof lid should be used, and warnings such as *"FOR ANIMAL TREATMENT"* included.

Drug administration

Parenteral or oral cytotoxic drugs should be administered only by a veterinarian. The administration of cytotoxic drugs should be done in accordance with standard procedures.

The examination table used for the recipient animal should be clearly signed with a cytotoxic label. After use, the table should be cleaned as soon as possible with water and alkaline detergent.

Patient care

Procedures to minimise exposure should be developed for workers handling patient blood, excreta etc.

Animal fluids and tissues should be handled using standard precautions. Patients receiving cytotoxic drug therapy should be placed in separate cages away from other animals where possible. A sign should be put on the cage to indicate that the patient is undergoing cytotoxic drug therapy. Phrases such as *'Cytotoxic drugs in use'*, *'must use latex gloves'* or *'excreta may be contaminated'* might be used. *"Carcinogenic"* may be a better term than *'cytotoxic'* in some situations, if it will be understood better by all staff working in the vicinity of the cages.

Patient waste

Generally, patient body substances will be contained in the cage after an animal has been treated with cytotoxic drugs. It is recommended that a special cage be provided which has a built-in flushing system which discharges directly into the sewerage system. If this is not possible, the animal should be placed in an isolated cage.

Cleaning animal cages

The following equipment is needed to clean cages:

- personal protective equipment (PPE) – gown, protective eyewear, disposable particulate respirator, two pairs of gloves, apron and rubber boots;
- absorbent pads;
- polythene bag with seal;
- spill towels (made of granular material);
- sodium hypochlorite or alkaline detergent, depending on the particular drug.

It is recommended that the following procedures for cleaning the cage be adopted:

1. Put on PPE and double glove.
2. Lay absorbent pad over wet excreta.
3. When excreta are absorbed, pick up absorbent pad and place in purple polythene bag.
4. Pick up faeces with spill towels and place in purple polythene bag.
5. Use spill towels and bleach to rinse the area, repeat several times.
6. Fully dry area with absorbent towels and place in purple polythene bag.
7. Clean cage with water and disinfectant avoiding splashes.
8. Remove outer gloves and place in purple polythene bag.
9. Seal polythene bag and place in second purple polythene bag along with other PPE (gown, mask and glasses). Do not fill bag more than three-quarters full.
10. Remove and discard inner gloves and seal the second bag.
11. Wash hands thoroughly with soap and water. Care should be taken to prevent generation of aerosols when dealing with contaminated body waste.

Cytotoxic spills

A spill kit should be available to deal with spills outside the cages, and recommended procedures followed. If an animal becomes contaminated it should be washed down, being careful not to generate aerosols.

Cytotoxic waste

Cytotoxic waste should be identified, segregated, contained and transported as recommended.. Such waste includes materials or equipment used in patient treatment, including:

- cytotoxic pharmaceuticals past recommended shelf life;
- sharps and syringes;
- IV infusion sets and containers;
- ampoules and vials;
- cotton wool from any bottles containing cytotoxic drugs;
- contaminated PPE – gloves, masks, disposable gowns etc;
- swabs and materials used to clean and contain spills;

- contaminated cleaning equipment.

Outpatient care at home

If cytotoxic drugs are prescribed for administration at home, they should be labelled and packaged correctly. Owners should be provided with written instructions regarding the need for special precautions during the period the drugs are excreted after treatment.

Equipment

The following should be available in the patient's home while receiving cytotoxic drug therapy:

- a supply of latex gloves (A pair of gloves is needed for single use, and then disposed of in household garbage.);
- flushable paper and paper towelling for cleaning up spills;
- detergent.

Administration of oral cytotoxic drugs

If tablets are to be administered by the owner, it is desirable that they be dispensed in the correct dosage. The breaking of tablets or capsules should be avoided wherever possible, by rounding of doses. Where it is necessary for owners to break tablets, they should be given proper instruction on how to do this safely without liberating powdered drug. Potential problems with ingestion or inhalation by the owner, and/or the contamination of surfaces, must be explained.

Owners should be advised that they should wear latex gloves when giving the tablet to the animal. The gloves should then be discarded with household garbage.

Patient waste

Owners should try to be aware of the area where the animal urinates so that the urine can be watered in well. They should be warned to be careful with the use of water to avoid splashing.

Animals should not be walked or allowed to roam in a public place during the period body wastes may be contaminated. To clean up excreta, scoop onto a non-absorbent implement such as shovel and dispose of in toilet. Wash the shovel under running water. Excreta which cannot be picked up should be diluted by hosing (without a jet) until it has been dispersed.

Laundry

Animal bedding or clothing of the handler with traces of contamination should be laundered immediately, and separately from other items. They should be washed in hot water on the longest wash cycle, and double rinsed.

Spills

A small quantity of patient waste spilled on the floor or on furniture should be dealt with as follows:

- Put on gloves.
- Wipe up spill with
 - flushable paper and double flush down the toilet with lid closed, or
 - disposable paper towelling or linen, placing the material in the cytotoxic waste bag.

- Clean area with water and detergent.
- Dispose of cleaning cloth and gloves in household rubbish.

It is best to use flushable paper wherever possible to reduce the amount of contaminated waste to be placed in household garbage.

Information for owners

Owners and other family members should exercise careful hygiene practices after handling pets receiving cytotoxic drugs. The time for particular care is during the period the drugs may be excreted.

Owners or custodians of animals receiving cytotoxic drug therapy should be provided with written information about the hazards of cytotoxic drugs, and precautions to be taken while caring for animal patients during the time the drug maybe excreted – usually about 48 hours. They should also be advised about special requirements of the particular drug used, including the approximate time high-risk residues may continue to be excreted after administration.

The following points should be covered in the written information for owners:

- reasons for taking precautions in the handling of cytotoxic drugs and related waste;
- precautions to take with interaction between the animal and people in the home - small children, the aged and women who are pregnant or breast feeding;
- how to store cytotoxic drugs at home;
- equipment which may be needed for the animal's care at home;
- route of excretion of drugs and how to dispose of body waste;
- spills and procedures for cleaning up;
- laundering contaminated bedding;
- emergency procedures for accidental exposure or accidental ingestion of cytotoxic drugs by children (eg telephone state/territory poisons information centre immediately – include the telephone number);
- disposal of drugs no longer needed by returning them to the clinic.

Further information

Details of recommended procedures and mandatory standards are available on the internet at

- <http://www.whs.qld.gov.au/guide/gde17.pdf>
- <http://www.workcare.sa.gov.au>
- <http://www.ohsrep.org.au>
- [http://www.workcover.vic.gov.au/dir090/vwa/publica.nsf/0/107b078308331fe2ca256cd7001af348/\\$FILE/handling_cytotoxic.pdf](http://www.workcover.vic.gov.au/dir090/vwa/publica.nsf/0/107b078308331fe2ca256cd7001af348/$FILE/handling_cytotoxic.pdf)

Another useful booklet, *Safe handling of cytotoxic drugs*, is available at <http://www.hse.gov.uk/pubns/misc615.pdf>

APPENDIX 9 Pharmacy Management

All practitioners are encouraged to adopt these standards for veterinary pharmacies.

1. The practice shall keep adequate supplies of veterinary medicines that shall be displayed or stored in a vermin-proof, clean, tidy, permanent, and secure building.
2. There shall be an efficient documentation system for the receipt of goods and timely unpacking to maintain manufacturers' recommendations regarding storage.
3. Smoking, eating, or the storage of food for human consumption shall not be permitted in areas where veterinary medicines are stored or dispensed.
4. Veterinary medicines shall be displayed or stored according to the manufacturers' instructions, and, where appropriate, protected from the adverse effects of light, temperature and humidity.
5. There shall be an efficient stock rotation system that prevents the use of out-of-date stock. Expired veterinary medicines shall not be prescribed or sold.
6. All Schedule 4 and 8 drugs shall be kept in a locked metal or wooden cupboard or a safe that is securely fixed. When the premises are unattended, the cupboard or safe shall be securely locked.
7. If it is necessary to carry a restricted drug in a vehicle, appropriate security must be maintained. Any Schedule 8 drug must be transported in a locked receptacle. Whenever the vehicle is unattended, the drugs should be secured, preferably in a locked boot. As far as practicable, the drugs should be kept at recommended temperatures, eg. by using a car refrigerator or icebox.
8. Tablets and capsules shall be dispensed in re-sealable and preferably crush-proof and child-proof containers.
9. Plastic or paper envelopes are unacceptable unless the product is marketed in a child-resistant pack (foil or plastic blister-pack). An exception is the use of pre-printed dog and cat wormer envelopes, provided the tablets dispensed are for the treatment of an individual animal only. Child-proof containers should be available if requested.
10. Adverse drug reaction report forms should be readily available in the clinic. These should be used to report all adverse drug reactions and apparent drug failures to the APVMA and to the manufacturer of the drug.
11. The container in which medicines and animal remedies are dispensed shall be legibly and indelibly labelled – see section 22.6
12. For food producing animals, veterinarians are ethically and legally obliged to supply sufficient information to clients to enable them to comply with their obligations in law. Accurate written or electronic records and accurate identification of individual animal treatment is essential.

APPENDIX 10 Order for Medicated Feed

Veterinary authorisation to supply feed containing a PAR antibiotic

1 To feed mill:

Name:

Address:.....

.....

Please provide the following feed for:

2 Farmer name:.....

Address:

Consign to:

3 **Medicated feed required**

Type of feed (eg broiler starter, porker):

.....

Form of feed (eg pellets, mash):.....

Quantity of medicated feed (order only as much as required):.....

Active ingredient:

.....

Inclusion rate (eg g/tonne) required:

.....

Product (trade name):

.....

Inclusion rate (eg kg/tonne) required

.....

4 **Animals to be treated**

Location:.....

Species:..... Type:

Age:..... Sex.....

Number:.....

5 **Directions for use of medicated feed on farm**

▪ Quantity of medicated feed to be given daily:.....

▪ Duration of treatment:.....

▪ Withholding period (**NOTE: medicated feed must NOT be fed during the withholding period**):

Do not slaughter animals for human consumption until days after their last consumption of medicated feed.

Eggs/milk must not be taken for human consumption until days after the last consumption of medicated feed.

- Precautions: Ensure that animals or birds other than those specified on this form do NOT have access to this medicated feed.

6 Veterinarian placing order:

Name:

Address:

.....

Telephone:.....

Signature:

Date: / /

[3 copies: Original - Feed mill, Copy 1 - Farmer, Copy 2 – Veterinarian]

APPENDIX 12 COMPANION ANIMAL PRESCRIPTION

This prescription is for ANIMAL USE ONLY

1. Prescribing veterinarian

Name.....

Practice name

Address

Contact details

SignatureDate.....

2. Prescription Animal Remedy/Prescription Medicine

Name

Strength

Quantity to be dispensed on each occasion

Instructions:

Dose

Frequency of dose

Route of administration

Duration of treatment

Number of repeat supplies(Period of treatment must not exceed 6 months supply)

Precautions

3. Owner (owner's agent) of animal(s)

Name

Address

Contact details

4. Animal(s)

Species.....

Name.....

NOTE: This prescription must be first dispensed within 30 days of the date of writing.

APPENDIX 13 PRODUCTION ANIMAL AUTHORISATION

This authorisation is FOR ANIMAL USE ONLY

1. Authorising veterinarian

Name.....

Practice name

Address

Contact details

SignatureDate.....

2. Prescription Animal Remedy (PAR)

Name.....

Active ingredient.....

Strength

Quantity to be dispensed on each occasion

Instructions:

Dose.....

Frequency or duration of dose

Route of administration

Where applicable:

Feed to which PAR is added

Quantity of feed to be supplied

Final concentration in feed or water

Number of repeat supplies(Period of treatment must not exceed six months supply)

Interval between each supply

Withholding period

Other precautions

NOTE: Animals must not be slaughtered until AFTER the withholding period has expired

3. Owner (owner’s agent) of animal(s):

Name.....

Farm name where applicable

Address

Contact details

4. Animal(s) description:

.....

NOTE: This prescription must be first dispensed within 30 days of the date of writing. It is recommended that copies of this prescription be kept by both the prescribing veterinarian, client and/or supply company, for audit purposes.

TO OUR CLIENTS

DISPENSING OF DRUGS

Please note that under the relevant law, any Prescription Animal Remedy (Schedule 4) or other restricted drugs can only be supplied to clients under the following conditions:

- **The animal(s) is under the care of a registered veterinarian,**
- **That veterinarian has sufficient knowledge of the medical condition of the animal(s) to prescribe appropriate treatment.**

By law, the supply of restricted drugs to clients is not permitted unless their animal(s) is on our records, or has been examined at this practice.

Accordingly, any owners travelling with animals requiring such medication will need to provide an authority from their own veterinarian before such drugs can be dispensed.

Alternatively, we will need to either contact that veterinarian and/or clinically examine the animal(s).

THANK YOU FOR YOUR COOPERATION.

APPENDIX 15 – AUSTRALIAN VETERINARY ASSOCIATION (AVA) CODE OF PRACTICE FOR PRESCRIPTION AND USE OF PRODUCTS WHICH CONTAIN ANTIMICROBIAL AGENTS

[Adopted 7 May 2008]

INTRODUCTION

The purpose of this Code of Practice is to raise awareness amongst prescribing veterinarians, and thus primary producers and the community, of issues related to the emergence and dissemination of antimicrobial resistance.

The Code of Practice should be read in conjunction with the AVA Guidelines for Prescribing, Authorising and Dispensing Veterinary Medicines (AVA Online) to which it is an appendix.

The Code is designed to help minimise the emergence and dissemination of resistance to antimicrobial agents and is consistent with the key recommendations of:

- The report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR 1999)
- World Health Organisation (WHO) Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food (WHO 2000)
- Antimicrobial resistance: responsible and prudent use of antimicrobial agents in veterinary medicine (Anthony et al 2001)
- AVA Policy on the Use of Veterinary Medicines. Part 2.2 Use of Antimicrobial Drugs in Veterinary Practice (AVA 1999)
- AVA Guidelines for Prescribing, Authorising and Dispensing Veterinary Medicines Appendix 1: Prudent use of antibiotics – Global basic principles (AVA 2005 Online).

It must be emphasised that continued availability of particular antimicrobial agents is at least in part contingent on the prudent prescribing practices of veterinarians as described by this Code of Practice and the AVA Guidelines for Prescribing, Authorising and Dispensing Veterinary Medicines.

Restraint statements on product labels, added to reduce antimicrobial resistance, may restrict prescribing rights and are enforceable under State/Territory control of use legislation. Veterinarians are obliged to comply with such regulatory label restraint statements and to observe the prescribing and dispensing requirements of veterinary registration legislation.

RESPONSIBILITIES OF THE PRESCRIBING VETERINARIAN

BACKGROUND

The AVA Policy on the Use of Veterinary Medicines (Part 2.2 Use of Antimicrobial Drugs in Veterinary Practice, Ratified by AVA Board 17 October 1999) states, in summary:

- Antimicrobial drugs (antibiotics) should only be administered, dispensed or prescribed on veterinary assessment of confirmed or suspected bacterial disease. AVA recognises that physical examination of every individual in a herd or flock is often not possible.
- Antimicrobials may be used to prevent bacterial overgrowth following viral illnesses, during anti-tumour therapy, in immunocompromised patients, in patients receiving glucocorticosteroids and following penetrating wounds.
- Veterinarians should stress to owners the importance of routine prophylaxis to reduce the risk of clinical bacterial disease and the need for antimicrobial therapy.
- Use of antibiotics can lead to resistant bacterial strains. Some bacteria can pass resistance genes to other bacteria. Antibiotic resistance can be passed from animals to humans through non-pathogenic bacteria able to pass resistance genes to pathogens.
- Concern re transmission of resistance from food producing animals to humans via contaminated animal products can be addressed by hygienic food preparation and cooking.
- Transmission of resistance to humans through contact with treated animals is possible. Farm workers and pet owners need to observe appropriate hygiene when handling animals to minimise exposure to resistant bacteria.

OBLIGATIONS OF THE PRESCRIBING VETERINARIAN

1. Assess clinical need before prescribing any antimicrobial products.
2. Follow this Code (the AVA CODE OF PRACTICE FOR PRESCRIPTION AND USE OF PRODUCTS WHICH CONTAIN ANTIMICROBIAL AGENTS)
3. Comply with prescribing requirements, including establishment of a legitimate veterinarian / user relationship before prescription.
4. Maintain records of the quantity of antimicrobial supplied.
5. Report all suspected adverse drug experiences including product failure due to (suspected) resistance.
6. Review patient or farm records on the use of products which contain antimicrobials to ensure compliance with prescribing label instructions.
7. Evaluate the response to previous treatment before again prescribing antimicrobials.
8. Maintain a high level of awareness of the problem of antimicrobial resistance in humans and prudent use of antimicrobials in animals and communicate this to clients.

RESPONSIBILITIES OF REGISTRANTS

The registrant or interested person is not necessarily a veterinarian, but practising veterinarians are often a source of new information that is passed on to registrants.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the body responsible for the registration of veterinary medicines (or chemicals) and operates in

accordance with the *Agricultural and Veterinary Chemicals Code Act 1994* (the AgVet Code).

The object of the AgVet Code is to make provision for the evaluation, approval, and control of the supply of active constituents for proposed or existing agricultural or veterinary chemical products and the evaluation, registration, and control of the manufacture and supply of agricultural and veterinary chemical products.

Under the AgVet Code “interested persons” in relation to registration issues is defined as the registrant (registration holder) of the registered product.

Section 161 of the Agvet Code states:

Notification of new information to APVMA

(1) If:

- (a) the interested person in relation to an approved active constituent for a proposed or existing chemical product or in relation to a registered chemical product; or
- (b) the holder of a permit in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product;

becomes aware of any relevant information in relation to the constituent or in relation to the product or of any of its constituents, the person must, as soon as practicable after the person becomes aware of the information, give that information to the APVMA.

(2) Information is relevant information if it:

- (a) contradicts any information given to the APVMA under this Code; or
- (b) shows that the use of, or any other dealing with, the constituent or the chemical product in accordance with the recommendations for its use or for such a dealing that the APVMA has approved:
 - (i) may be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; or
 - (ii) may be likely to have an effect that is harmful to human beings; or
 - (iii) may be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; or
- (c) shows that the use of the product in accordance with the recommendations for its use that the APVMA has approved may be ineffective according to criteria determined by the APVMA for the product; or
- (d) would have had to be given to the APVMA in connection with the application for the approval, registration or permit if the applicant had been aware of the information when the application was made.

(3) Any information that a person has to give to the APVMA under this section must be given in writing signed by an approved person.

Key responsibilities of registrants that impact on the continuing rational use of antimicrobial agents are:

1. To report adverse experiences to the APVMA's adverse experience reporting program (AERP), and
2. To report new information relevant to the product to the APVMA.

RESPONSIBILITIES OF USERS

Veterinarians occupy an important and critical position in the provision of information to users on the benefits and risks of the veterinary medicines they prescribe. Once informed, the users of antimicrobial agents have the following responsibilities:

1. To not use products which contain antimicrobials as a substitute for good feeding practice and good animal husbandry practice, and
2. To use products according to label instructions or following written veterinary instructions

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ANNEX OF SPECIAL SITUATIONS

Fermentative acidosis in ruminants

Fermentative acidosis refers to a series of conditions that reflect a decrease in pH in the fermentation compartments of the ruminant gut, principally the rumen but occasionally the caecum. Rumen lactic acidosis (grain overload, grain poisoning, acute indigestion) develops in sheep and cattle that have ingested large amounts of unaccustomed feeds rich in fermentable carbohydrates. The resulting production of large quantities of volatile fatty acids (VFA) and lactic acid decreases rumen pH to non-physiological levels, simultaneously weakening the buffering capacity of the rumen and reducing the efficiency of rumen flora and fermentation. Lactic acidosis can be divided into two categories – clinical and sub-clinical, and can cause rumenitis, metabolic acidosis, lameness, hepatic abscessation, pneumonia and death.

The Reference Advisory Group on Fermentative Acidosis of Ruminants (RAGFAR), a subcommittee of the AVA Therapeutics Advisory Committee, has prepared a detailed monograph entitled "Ruminal Acidosis – aetiopathogenesis, prevention and treatment. A review for veterinarians and nutritional professionals (July 2007) which is on the AVA website. This document highlights how forward planning and preventative management can frequently avoid the onset of fermentative acidosis. Whenever possible the use of non-antibiotic options is recommended prior to decisions to employ antimicrobial interventions. Amongst the strategies described in the RAGFAR

monograph are attention to the nutritional and animal husbandry contributions to the pathophysiology of fermentative acidosis.

Necrotic enteritis in poultry

Necrotic enteritis (NE) is an enteric bacterial infection caused by *Clostridium perfringens* which is characterised by sudden increases in mortality of up to 20% (not infrequently 1% per day) with up to 37% birds affected, usually in 2–6 week-old broilers raised on litter. NE frequently occurs concurrently with coccidiosis with which it may initially be confused. NE has been reported from most areas of the world where poultry are produced and is an important disease in Australia.

Wherever possible preventative strategies are recommended and non-antimicrobial options should be considered before use of antimicrobial agents.

When antimicrobial agents are selected for use, such use should be in accord with the recommendations set out in Appendix 3 Use of Veterinary Medicines in the Poultry Industry (pages 45-50).

Specific guidelines for use of products that contain virginiamycin

For each clinical and animal husbandry situation associated with a finite risk of necrotic enteritis of poultry or fermentative acidosis in ruminants, veterinarians should first consider management by means that do not require an antimicrobial agent. If virginiamycin is indicated a treatment protocol that minimises the duration and frequency of treatment should be implemented.

Examples of clinical and animal husbandry situations associated with fermentative acidosis include:

- introduction of heifers to the dairy herd
- high-producing dairy cows consuming high levels of fermentable carbohydrate
- introduction of cattle to feedlot rations
- re-introduction of feedlot cattle to feedlot rations after low feed intake (for example, following period of heat stress)
- drought feeding of sheep or cattle.