

# **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

## **REFERENCES**

- Anthony F, Acar J, Franklin A, Gupta R, Nicholls T, Tamura Y, Thompson S, Threlfall EJ, Vose D, van Vuuren M, White DG; Office International des Epizooties Ad hoc Group. (2001). Antimicrobial resistance: responsible and prudent use of antimicrobial agents in veterinary medicine. *Rev Sci Tech* 20(3): 829-839
- AVA (1999). Policy on the Use of Veterinary Medicines. Part 2.2 Use of Antimicrobial Drugs in Veterinary Practice. Ratified by AVA Board 17 October 1999
- JETACAR (1999). The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans. Report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance. Commonwealth of Australia, Canberra.
- WHO (2000). WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food. WHO/CDS/CSR/APH/2000.4

## **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.