APVMA Advisory Board
Futures Forum 2014
Future Directions of Veterinary Medicines
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About the AVA

• 8,500 members
• 53% of registered vets
• Members involved in clinical practice, biosecurity, all levels of government, industry, research and teaching
• Veterinarians can prescribe and dispense
Strategic priorities

Planning an effective workforce
Ensuring economic sustainability
Better regulation
Filling the gap in Government services
Anti microbial resistance
Antimicrobial resistance

Concerns and activities
• AVA involved in many forums
• One Health participant
• Food safety
• Food supply
• Treatment and prevention of existing and novel diseases

What are we doing?
• Raise awareness amongst profession
• Educate animal owners
• Promote stewardship
• Publish guidelines
The future in a world of AMR

• Fewer antibiotics registered
• Restrictions on use of existing registered products
• Need for consideration of novel therapies
• More personalised medicine
• Food safety? And supply?
• Intensive farming?
• More complementary remedies
Compounding

- Growth area, largely unregulated
- Legislative requirements vary and can be contradictory
- Safety and efficacy data lacking
- Stability and use by dates
- Aggressive marketing to vets and animal owners
- Price competitiveness with registered product
- Dispensing on anticipated need not for specific animal
- No agency to report adverse reactions
- Pharmacist training is in human medicine
Why do we need them?

- Companion animals come in all sizes, medications do not.
- Compliance with unpalatable medications.
- Presentation unsuitable for animals.
- Very few medications registered for companion animals compared to need.
- Wildlife, birds, fish and exotics.
Introduction

These guidelines have been produced to assist members in making informed decisions about the appropriate use of compounded medicines in veterinary practice. Compounded pharmaceuticals are unregistered veterinary medicines that form an important part of a veterinarian's arsenal in treating their patients. Unlike registered veterinary medicines, they are not subject to rigorous assessment for product quality, efficacy and safety by the Australian Pesticides & Veterinary Medicines Authority (APVMA) and therefore may carry a greater risk than registered products when used to treat animals. As with all medicines, veterinarians must understand and comply with all legal requirements for preparation and use of compounded medicines in accordance with national, state and territory control of use and drugs and poisons legislation. The use of an unregistered veterinary medicine when a suitable registered medicine is available is not considered best practice.

Guidelines for the prescription and use of compounded medicines:

Products compounded by pharmacists (if prepared in accordance with the instruction of a veterinarian) or veterinarians are not defined as veterinary chemical products (Agricultural and Veterinary Chemicals Code Act 1995 Section 5(4)), and are therefore exempt from registration by the Australian Pesticides & Veterinary Medicines Authority (APVMA) and are referred to as unregistered veterinary chemicals according to control of use legislation.

1. Veterinarians are authorised to compound veterinary medicines or instruct a pharmacist to compound a veterinary medicine, under the Agricultural and Veterinary Chemicals Code Act 1995 Section 5(4). However, legislative requirements are placed on their preparation and use. Compounding pharmacists may only compound on written instruction or on prescription and veterinary practitioners may only prescribe a product for compounding that is sufficient quantity for the particular animal(s) to be treated. There is no provision in the state and territory control of use and drugs and poisons legislation for the preparation and storage of compounded veterinary pharmaceutical products for use in other animals at a later date. As with all dispensed medicines, compounded medicines must be labelled with all details required on a prescription specific to the animal that is being treated, as required under state and territory legislation.

For example, in Victoria the name or species of the animal and the name of the owner or person having custody of the animal must be on the label while other states require only the species and owner's name (Victorian Drugs, Poisons and Controlled Substances Regulations 2006: Reg 29 Containers of drugs to be labelled with certain details; NSW Poisons and Therapeutic Goods Regulation 2008: Appendix A Labelling of Therapeutic Substances).

2. Veterinarians may compound medicines in the course of their practice, and supply that medicine to the owner of an animal, for use on their animal under the veterinarian's care. It is a breach of state and territory drugs and poisons legislation to 'onself' any restricted veterinary product (S4 or S8 or unregistered veterinary chemical) to other veterinarians without appropriate licensing.
The future for compounded medicines

- Legislative change or just legislation..
- Voluntary controls, compliance and GMP registration
- Agency to collect adverse events (including ineffectiveness)
- Animal medicine manufacturers reluctant to take a product to market
Other concerns of AVA

- On-line pharmacies
- Organic farming
- Availability of analgesics for common husbandry procedures
- Parasiticide resistance
- Aquaculture and the use of antimicrobials
- Development and registration of vaccines
- Complementary medicine
Case studies

• Hendra vaccination
  – Minor use permit
  – No formal registration
  – Extended duration of protection
  – Adverse event reporting

• Use of chloramphenicol for treatment of chlamydyosis in koalas
Summary

• Less not more registered remedies
• Inability to treat common diseases
• Inability to respond to EIDs
• Likely emergence of more zoonoses
• How to feed a hungry world?
• More demand for complementary/alternative remedies