



Australian Veterinary Association Ltd

Guidelines for the preparation and use of compounded pharmaceuticals

Introduction

These guidelines have been produced to assist members in making informed decisions about the appropriate use of compounded medicines in veterinary practice.

Veterinary compounding is the preparation of medicine, either by a veterinarian, or by a pharmacist on the instructions of a veterinarian, to meet the specific needs of an individual patient. Compounding is sometimes called extemporaneous preparation or manufacturing, as the medicine is made up at the time it is needed and for a specific patient or patients. Compounded products are not defined as veterinary chemical products in the AgVet Code, and are therefore exempt from registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Compounded medicines may form an important part of a veterinarian's arsenal in treating their patients.

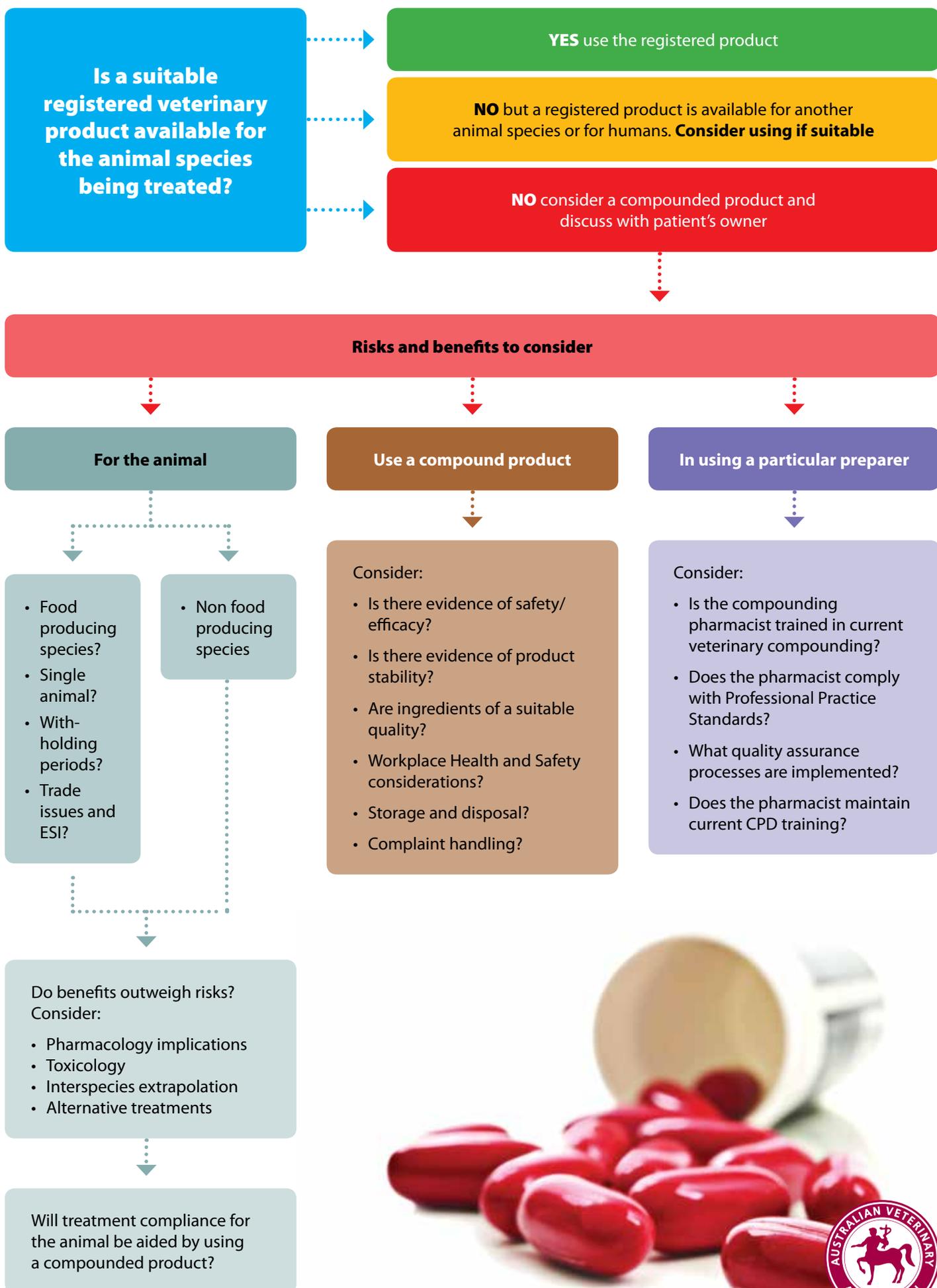
Unlike registered veterinary medicines, compounded medicines are not subject to rigorous assessment for product quality, efficacy and safety by the APVMA and may carry a greater risk than registered products when used to treat animals. As with all medicines, veterinarians must understand and comply with 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.

Using an unregistered veterinary medicine when a suitable registered medicine is available is not considered best practice.

When to use compounded products

All species deserve the benefit of medicinal products which are most suitable for their particular needs. The decision flow chart (page 2) and summary guidelines (page 4) provide a systematic, best-practice approach to ensure this happens wherever possible. Following these guidelines, veterinary practitioners may use their clinical judgement to prescribe a compounded medicine where no suitable registered veterinary product is available. A medicine prescribed following this decision process may be administered by the prescribing veterinarian or by a person acting under their direction. Responsibility for the prescription and use of the medicine remains with the prescribing veterinary practitioner.

Decision flow chart for use of compounded products by veterinarians



Key questions to ask your compounding pharmacist



Does the pharmacist have experience and training in complex compounding of veterinary products and comply with the Pharmacy Board of Australia Compounding Guidelines and published pharmacy practice standards on compounding?

What quality assurance programs are in place?

What are the Standard Operating Procedures (SOPs) in case of a recall, complaint or adverse reaction?

Do sterile compounding facilities comply with the Australian Standards for clean rooms and is there a sterility testing program in place?

Does the pharmacist have or have access to the appropriate texts and reference books for animal dosages and side effects?

Compounded medicines must be prepared by pharmacists according to the accepted professional standards as set out in the Pharmaceutical Society of Australia's Professional Practice standards (standards 10 and 11, www.psa.org.au)

Similar experience, training, quality assurance programs and recall, complaint and adverse reaction systems should apply to compounding veterinarians.

It is recommended that veterinarians ask some simple questions of their pharmacist prior to selecting a compounding pharmacist and having prescriptions filled.

Summary: Guidelines for the prescription and use of compounded medicines

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.

Compounding pharmacists may compound only on written veterinary instruction or veterinary prescription.

A compounded preparation should only be used in circumstances where a commercial product is unavailable or unsuitable.

Veterinarians may only prescribe a product for compounding in **sufficient quantity** for the particular animal(s) to be treated. State and territory control of use and drugs and poisons legislation do not generally provide for the preparation and storage of compounded veterinary pharmaceutical products for use in other animals at a later date. There are some exceptions – see sections 5–6 in the FAQs, below.

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. It is good practice to include details identifying the active constituents, the animal to be treated, instructions for use, the owner and the prescribing veterinarian. For more information on labelling see section 1 in the FAQs, below.

Additional restrictions apply to supply of unregistered veterinary medicines for use in **food-producing animals**. A veterinary practitioner may supply or compound a veterinary medicine for use in a single food producing animal, according to his / her prescribing rights, governed by the laws in the particular state or territory. Veterinarians should check their particular state and territory prescribing rights as there may be some variation.

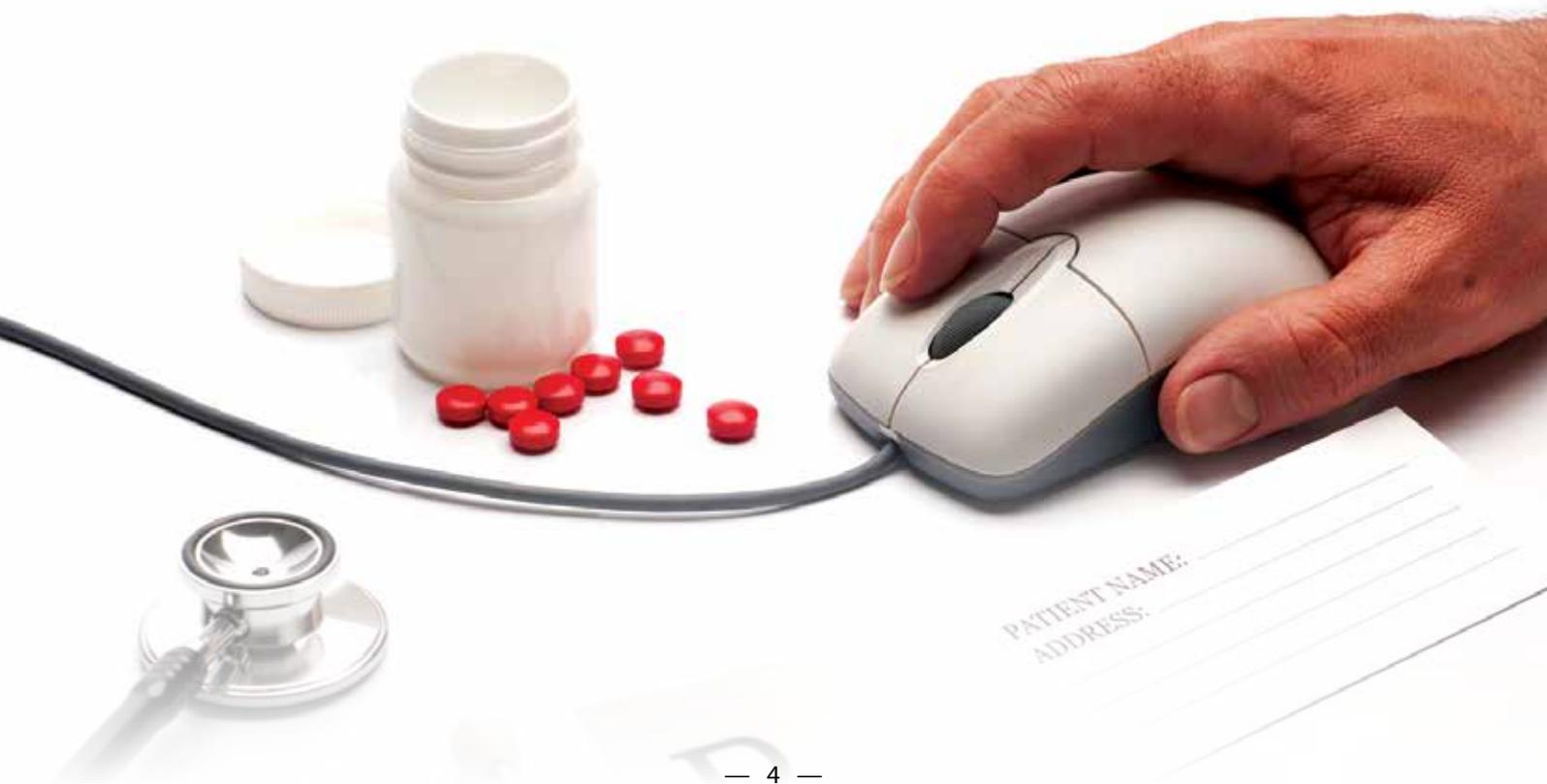
The veterinarian and pharmacist have certain **responsibilities**. The veterinarian prescribing or supplying a compounded product should first discuss the benefits and risks associated with the use of the product with the client. For compounded products, the veterinarian is responsible for providing instructions to the pharmacist for compounding of the products and the required label directions for use. The compounding pharmacist is responsible for the accurate filling of the veterinarian's prescription. The prescribing veterinarian and/ or the compounding pharmacist may be liable for harm due to side effects or lack of efficacy. Special care must be taken to ensure that excessive residues do not occur in food-producing or performance animals.

The decision to use any therapeutic intervention, including the use of a compounded medicine should be made by the veterinarian (not a client or a pharmacist), based on a genuine **veterinarian-client-patient relationship**. Whenever possible the veterinarian should make that decision using evidence-based medicine.

It is a breach of state and territory drugs and poisons legislation to **'on-sell'** any restricted veterinary product (any S4 or S8 or unregistered veterinary chemical) to other veterinarians without an appropriate wholesaler's licence.¹

Compounded products are intended for immediate usage and so unless otherwise stated, an **expiry date** 28 days from the date of manufacture applies. In some cases the expiry period will be much shorter. No product should be supplied after the expiry date. Stability testing is not required for compounded products so an extended shelf life cannot be guaranteed without the support of specific evidence. See section 4 in the FAQs below.

1. In the Northern Territory, pharmacists may supply by wholesale without a separate wholesaler licence – see sections 35 and 57 of the *Medicines, Poisons and Therapeutic Goods Act 2012 (NT)*.



FAQs – prescribing and using compounded medications

1. What details are required on the drug label of a compounded medication?

- 1.1 Although there is no requirement to include the name and address of the prescribing veterinarian or clinic on the pharmacist's label, it is good practice to do so. If the medication is supplied by the pharmacist to the prescribing veterinarian and then dispensed to the animal's owner by the veterinarian, it is good practice (and in some states and territories it is mandatory) for the veterinarian to add his / her own label.
- 1.2 The veterinarian's label must not cover or obscure the pharmacist's label and should contain the veterinarian's name and contact details.
- 1.3 It is good practice to include the name or identification details of the patient animal on the label. In some states, including Tasmania and the ACT, it is mandatory. (In the ACT, such details only need to be included if the animal has a specific name or can otherwise be specifically identified.) The label should also contain the species of the patient animal and the name of the animal's owner, or custodian. In Tasmania, the address of the animal's owner is required as well.

2. Can I trust compounded medications made by a pharmacist or compounding pharmacy?

- 2.1 Pharmacists are subject to:
 - stringent professional obligations under the supervision of the Pharmacy Board of Australia and its state / territory branches;
 - the Health Practitioner Regulation National Law Act (which does not apply to veterinarians);
 - Agvet and poisons / therapeutic goods legislation at the state / territory level, which is enforced by the agriculture and health departments of the various state / territory governments (see section 16 for a list of this legislation); and
 - the general law, including tort law (e.g. professional negligence), which applies to all health care professionals.
- 2.2 Accordingly, the pharmacy industry is heavily regulated and, like all health care professionals, pharmacists must discharge a professional duty of care to the owners of treated animals. Nevertheless, there can be significant quality variations between compounding pharmacies.

3. How should I, as a veterinarian, choose a compounding pharmacy?

- 3.1 Veterinarians are encouraged to observe the following guidance in selecting a quality compounder:

CGMP compliance and quality control

Veterinarians should check whether the compounding pharmacy's facilities and processes comply with the Code of Good Manufacturing Practice (CGMP). The CGMP requires a strict quality assurance regime and consistent monitoring of manufacturing processes under regulatory supervision. Premises that are licensed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) have established compliance with CGMP standards. Whenever possible, a CGMP-compliant compounder should be preferred.

Veterinarians should also enquire as to whether the compounding pharmacy has evidence of the safety, efficacy and stability of the relevant medication before it is prescribed and whether the pharmacy has a formal Adverse Drug Reaction (ADR) program.

Competency for complex compounding

Veterinarians should also be aware of the distinction between "simple compounding" and "complex compounding". "Complex compounding" is compounding that requires or involves specific competencies, equipment, processes or facilities – such as for:

- sterile preparations;
- preparations containing ingredients that may pose an occupational health and safety hazard such as cytotoxics or hormones;
- preparations containing monoclonal antibodies;
- micro-dose single unit dosage forms containing less than 25mg of active ingredient (or less than 25% by weight or volume) per dose; and
- tablets, capsules, troches and sustained-release or other modified release preparations.

Because complex compounding requires a higher level of competency, pharmacists who wish to engage in complex compounding must acquire and build the requisite knowledge and expertise through participation in formal continuing professional development (CPD) activities and ongoing workplace training and experience. Accordingly, veterinarians should specifically enquire as to the pharmacist's expertise and experience in complex compounding before ordering any complex compounded products.

Staff training

Veterinarians should enquire as to whether employees of the pharmacy are comprehensively trained to ensure that their knowledge, competency and manual handling skills are of an appropriate standard for the preparation of extemporaneous preparations.

Veterinary compounding

As veterinary compounding is a specialised form of pharmaceutical compounding, veterinarians should additionally enquire as to what experience the pharmacy has in veterinary compounding in particular and whether the pharmacy trains its staff in veterinary compounding specifically.

4. What is the shelf life of compounded products?

- 4.1 In general, all medications have a “use by” (otherwise referred to as “beyond use”) date that should be stated on the pharmacist’s label. 28 days from date of manufacture is the default expiry period if nothing is stated.
- 4.2 High-quality compounders will often conduct appropriately controlled stability testing to ascertain the shelf life of their compounded medications under the intended storage conditions. Veterinarians should enquire as to what stability testing the compounding pharmacy has conducted and, whenever possible, should select a compounding pharmacy that conducts appropriate stability testing in line with the Code of Good Manufacturing Practice – see section 3.

5. How much compounded medication can I order at one time?

- 5.1 The general rule is that, when ordering a compounded medication by way of a prescription (as opposed to other types of orders), the quantity must accord with the recognised therapeutic standard of what is appropriate to treat the specific animal(s) in the relevant circumstances.
- 5.2 In Queensland and the Northern Territory, this is generally limited to a single course of treatment only. However, for non-food-producing animals, the Queensland legislation appears to allow that a single prescription may request a bulk quantity that covers multiple animals.²
- 5.3 In Victoria, for S4 and S8 medications, requests to dispense more than “appears to be reasonably necessary” must be reported to the regulator. However, the Victorian legislation specifically allows that S4 medications may be ordered “in bulk for treatment of flocks or herds of animals”.³
- 5.4 The South Australian legislation contains a regime that permits veterinarians to order S4 medications by way of “written orders”, as opposed to prescriptions. Similarly, that regime specifically contemplates that a written order may request a bulk quantity that covers the “mass treatment of certain animals”.⁴ The legislation does not clearly prescribe the form requirements for such a written order – however, it does distinguish such written orders from formal prescriptions⁵ and it appears that the form requirements for prescriptions⁶ do not apply to such written orders.
- 5.5 The New South Wales legislation contains a regime that permits veterinarians to order S4 medications by way of “written orders” (as opposed to prescriptions) where the medication is supplied “for emergency use”.⁷ The phrase “for emergency use” is purposive and appears to permit S4 medications to be ordered in advance, and in bulk, for the purpose of use in reasonably anticipated future emergencies. In reliance upon this exception, veterinarians should only order medications that are for use in genuine, reasonably anticipated emergency situations, taking into account:
 - the likelihood and expected timing of an emergency arising;
 - the potential clinical consequences of any failure to have the required medication on hand when needed; and
 - the medicinal effects of the relevant medication.

6. Can I order compounded medication to keep available for emergencies?

- 6.1 In general, veterinarians should not order, by way of a prescription, medications that will be stored for use in potential emergencies for as yet unidentified patient animals – instead, such requests should be placed by way of a “written order” where permitted under relevant state / territory legislation.
- 6.2 In NSW, the ability of veterinarians to place such orders is clear (see section 5.5 above). Similarly, for S4 medications, such orders may be permitted in Queensland⁸, South Australia⁹ and the ACT¹⁰ and, if the supply by the pharmacist is considered to be supply by wholesale, the Northern Territory as well¹¹. It also appears that such orders are permitted in Tasmania for S3 medications¹². The position is unclear in Victoria and Western Australia.
- 6.3 Veterinarians should only:
 - place such pre-emptive orders in relation to medications that are for use in genuine, reasonably anticipated emergency situations; and
 - store such medications in quantities that are reasonable taking into account the likelihood and expected timing of relevant emergency situations arising.

2. Section 12J of the *Chemical Usage (Agricultural and Veterinary) Control Act 1988* (QLD).

3. Section 29 of the *Drugs, Poisons and Controlled Substances Regulations 2006* (VIC).

4. Section 21 of the *Controlled Substances (Poisons) Regulations 2011* (SA).

5. Section 36 of the *Controlled Substances (Poisons) Regulations 2011* (SA).

6. Section 34 of the *Controlled Substances (Poisons) Regulations 2011* (SA).

7. Section 46 of the *Poisons and Therapeutic Goods Regulation 2008* (NSW).

8. Section 200 of the *Health (Drugs and Poisons) Regulation 1996* (QLD).

9. Section 21(2)(b) of the *Controlled Substances (Poisons) Regulations 2011* (SA).

10. Sections 60, 62 and Schedule 1 of the *Medicines, Poisons and Therapeutic Goods Regulation 2008* (ACT).

11. Sections 35 and 57 of the *Medicines, Poisons and Therapeutic Goods Act 2012* (NT).

12. Section 53 of the *Poisons Regulations 2008* (TAS).

7. Can a veterinarian use a compounded medication on multiple animals from the same bottle?

- 7.1 This should be avoided, because of the increased risks associated with sharing medication from the same container – such as greater risk of contamination, and difficulty keeping records as to which patients have been treated with the medication, etc). However, if this cannot practicably be avoided, then it may be permitted in some states / territories if:
- **Same owner:** if all of the animals have the same owner (or, in Victoria, are in the custody of the same person). In all states / territories other than Tasmania and the ACT, a prescription does not need to identify any specific patient animal and rather only needs to specify the relevant species. Additionally, state / territory legislation may permit a single prescription to cover multiple animals – see section 5. Accordingly, there may be circumstances in which a prescription for a single container of medication may cover multiple animals that have the same owner (or, in Victoria, are in the custody of the same person);
 - **Emergency use:** if the medication was validly obtained for the purposes of potential emergency use. For example, in New South Wales, a pharmacist may supply a veterinarian with a S4 medication for the purposes of future emergency use upon a written order, which does not need to relate to any particular animal(s) or owner. It may therefore be possible for a single container of medication so obtained to be used to treat multiple animals, even with different owners, in genuine emergency situations. See sections 5.5 and 10 for more detail; or
 - **Treatment of flocks / herds:** the medication is being used to treat a particular group of animals. For example, in Victoria and South Australia, a veterinarian may order medication in bulk for the mass treatment of a particular group (e.g. a flock or herd) of animals. See section 5 for more detail. Note that some states / territories severely limit the use of unregistered products in food-producing animals – for example, the ACT prohibits such treatments, while NSW allows only one animal to be treated in any herd or flock on a particular day.

8. Who is responsible when an adverse reaction or event occurs in an animal that has been treated with a compounded medication?

- 8.1 This will depend upon the particular circumstances of the relevant case. For example, if the pharmacist has failed to provide the correct medication or has otherwise been negligent in the preparation of the medication, then the pharmacist would bear responsibility. Similarly, if the veterinarian has prescribed the wrong medication, has failed to advise the owner adequately in regard to its safe use, or has otherwise been negligent in its storage or application to the patient animal, then naturally the veterinarian would bear responsibility.
- 8.2 Both the pharmacist and the veterinarian are professionals who:
- must work to accepted professional standards;
 - owe a duty of care to patients; and
 - are subject to the general law, including tort law (e.g., professional negligence).

9. Can I mark up and put a dispensing fee on compounded medications?

- 9.1 Yes.

10. If I have compounded medications made up for multiple animals, does this constitute wholesaling?

- 10.1 In general, where practicable, compounded medications should be ordered by prescription for individual patient animals – however, there are a number of situations in which a veterinarian might need to order compounded medications in bulk and / or for multiple animals – for example, when treating multiple animals of the same owner or a flock or herd of animals or ordering for the purposes of reasonably foreseeable emergency use.
- 10.2 Ordering medications in bulk and / or for multiple animals does not necessarily constitute wholesaling. As a general rule, wholesaling is supply with the primary purpose of on-supply (i.e., where person “A” supplies a medication to person “B” principally for the purpose of person “B” on-supplying that medication to person “C”). Accordingly, supply by a pharmacist to a veterinarian in bulk will generally not be considered wholesaling unless a primary purpose of that supply is on-supply by the veterinarian.
- 10.3 Any such bulk supply will need to comply with the quantity limitations discussed in section 5. See section 7 in relation to treating multiple animals from the same container.

11. Can I use price as a defence as the reason why I chose a compounded medication over a registered product?

- 11.1 Veterinarians should only prescribe a compounded medication where there is a clinical advantage to using a compounded option – such as a more appropriate dosage form, flavouring or method of administration – or when no appropriate registered product is available. Accordingly, if an appropriate registered product is available and there is no clinical advantage to using a compounded medication, veterinarians should suggest only the registered product in the first instance, even if an appropriate compounded alternative is more affordable.



- 11.2 However, in such a circumstance, if the patient animal's owner then rejects treatment on the basis that the recommended registered product is too expensive, the fundamental ethical / moral and professional duties of veterinary medicine may dictate that the veterinarian should then bring the availability of the compounded alternative to the attention of the patient animal's owner in an effort to avoid the animal unnecessarily suffering or even dying as a result of being left untreated.
- 11.3 It must be emphasised that choosing a compounded medication over an available registered product on the basis of price alone (i.e., where an appropriate registered product is available and there is no advantage to using the compounded alternative other than pricing) should only occur where:
- the veterinarian has recommended only the registered product in the first instance, making no mention of the cheaper compounded alternative;
 - the patient animal's owner has then refused treatment with the registered product on the basis of price; and
 - the veterinarian has then clearly confirmed that the sole or dominant reason for the owner's refusal of treatment is that the registered product is not affordable for that owner on that occasion.
- 11.4 In other words, if price is the only reason to choose a compounded medication over an available registered product, the veterinarian should only prescribe the compounded alternative once the specific sequence of events described above has taken place. Please note, however, that prescribing the compounded alternative in that scenario is not only permitted but conceivably also ethically / morally and professionally demanded, as the welfare of the animal should be the primary concern of the veterinarian.

12. Can an animal owner ask that their veterinarian use a compounded medication instead?

- 12.1 An owner may ask their veterinarian to use a compounded medication instead of a registered product but the veterinarian is not required to follow that request and retains his / her professional discretion as to how to treat the patient animal. Although the veterinarian is not bound to follow such a request, in general veterinarians must not administer any treatment without the consent of the owner or custodian of the animal.

13. Do I have to follow the AVA guidelines for use when using compounded medications?

- 13.1 The AVA guidelines are not binding as a matter of law but should be held in high regard by veterinarians and importantly may be used as evidence in establishing accepted professional standards in connection with any claim of unprofessional conduct and / or negligence that may be brought against a veterinarian.

14. What is the withholding period of using compounded medications in performance horses?

- 14.1 As with registered medications, this will depend upon the particular chemical compounds, the formulation involved, the dosage and the characteristics of the patient animal. Where possible, the veterinarian should give advice on an appropriate withholding period. Applicable screening limits and recommended withdrawal times of compounded medications should be confirmed with the relevant racing or other sporting regulatory authority.

15. Why don't veterinarians use compounded medications more often?

- 15.1 As explained in section 11, as a general rule, veterinarians should only prescribe compounded medications where there is a clinical advantage to using a compounded option or no appropriate registered product is available. This is primarily because registered medications must be shown to be effective and safe and must be manufactured in accordance with the Code of Good Manufacturing Practice (CGMP), whereas compounded medications are not subject to the same requirements. This means that quality may vary between different compounding pharmacies. Accordingly, as explained in section 3, a CGMP-compliant compounder should be preferred.

16. What are the “control of use” and “poisons / therapeutic goods” laws that regulate my use of compounded medication as a veterinarian?

New South Wales

Stock Medicines Act 1989
Stock Medicines Regulation 2010
Poisons and Therapeutic Goods Act 1966
Poisons and Therapeutic Goods Regulation 2008

Victoria

Agricultural and Veterinary Chemicals (Control of Use) Act 1992
Agricultural and Veterinary Chemicals (Control of Use) Regulations 2007
Drugs, Poisons and Controlled Substances Act 1981
Drugs, Poisons and Controlled Substances Regulations 2006

Queensland

Chemical Usage (Agricultural and Veterinary) Control Act 1988
Chemical Usage (Agricultural and Veterinary) Control Regulation 1999
Health (Drugs and Poisons) Regulation 1996
Health Regulation, 1996

Western Australia

Veterinary Chemical Control and Animal Feeding Stuffs Act 1976
Veterinary Chemical Control Regulations 2006
Poisons Act 1964
Poisons Regulations 1965

South Australia

Agricultural and Veterinary Products (Control of Use) Act 2002
Agricultural and Veterinary Products (Control of Use) Regulations 2004
Controlled Substances Act 1984
Controlled Substances (Poisons) Regulations 2011

Tasmania

Agricultural and Veterinary Chemicals (Control of Use) Act 1995
Agricultural and Veterinary Chemicals (Control of Use) Regulations 2012
Agricultural and Veterinary Chemicals (Control Of Use) Order 2001
Code of Practice for the Supply and Use of Veterinary Chemical Products
Poisons Act 1971
Poisons Regulations 2008

Australian Capital Territory

Environment Protection Regulation 2005
Medicines, Poisons and Therapeutic Goods Act 2008
Medicines, Poisons and Therapeutic Goods Regulation 2008

Northern Territory

Agricultural and Veterinary Chemicals (Control of Use) Act 2004
Agricultural and Veterinary Chemicals (Control of Use) Regulation
Medicines, Poisons and Therapeutic Goods Act 2012
Medicines, Poisons and Therapeutic Goods Regulations

16.1 Veterinarians should also be aware of:

- The *Standard for the Uniform Scheduling of Medicines and Poisons*, otherwise known as the ‘Poisons Standard’ or ‘SUSMP’;
- and the veterinary practice legislation and codes of conduct applicable in the jurisdiction in which they are registered.

Scenarios

Scenario A

Sarah is a young graduate who has been working at an established mixed animal practice for the last 18 months. She has noticed that there is a lot of compounded medication on the shelf for treating cardiovascular disease in small animals; some individual items she knows have been on the shelf for longer than three months. Sarah is concerned that if she uses the drugs, she may be breaking the law.

Response

Every package of medication, whether registered or compounded, should have its “use by” (otherwise referred to as “beyond use”) date or shelf life stated on the label or container (see section 4 of the FAQs). Sarah should not use any medication that has passed its use-by date. She should also confirm that all of the medication that is stored on the shelf has been stored appropriately according to the label and obtained on a bona fide basis for the purposes of reasonably anticipated emergency use in accordance with relevant state / territory legislation (see section 6 of the FAQs).

Scenario B

A herd of mares is being synchronised for reproductive purposes during the breeding season using a compounded medication. If a vet is using the same bottle for multiple horses on the farm which belong to different owners, whose name should appear on the label?

Response

In general, veterinarians should avoid treating animals that have different owners with medication from the same container. However, depending upon the applicable state/territory and circumstances, this may be permitted (see section 7 of the FAQs for more detail).

Scenario C

A vet has a client who has indicated that they have limited financial capacity to treat a serious life-threatening illness in their 6-year-old pleasure horse. There is a compounded medication available which is reported to be of some benefit and is far cheaper than the registered product. If the vet prescribes the compounded medication in favour of the registered product is he / she breaking the law?

Response

See section 11 of the FAQs for a discussion on this issue.

Note: these Compounding Guidelines are intended as a general guide and should not be relied upon as legal advice. Veterinarians should familiarise themselves with the specific requirements of the jurisdiction(s) in which they work. The Guidelines will be updated regularly. Suggestions for improvements should be forwarded to: melanie.latter@ava.com.au