AUSTRALIAN VETERINARY ASSOCIATION

Guidelines for the preparation and use of compounded pharmaceuticals

Introduction

These guidelines have been produced to assist veterinarians to make informed decisions about the appropriate use of compounded medications in veterinary practice.

Veterinary compounding is the preparation of medications by a veterinarian, or by a pharmacist on the instructions of a veterinarian, to meet the specific needs of animal patients. Compounding is sometimes called *extemporaneous preparation* or *extemporaneous manufacturing*, as the medication is commonly 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[1] and, are therefore exempt from registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Compounded medications may form an important part of a veterinarian's arsenal in treating their patients; however, rules that apply both to veterinarians and pharmacists regulate their preparation and supply.

Unlike registered veterinary medicines, compounded medications are not subject to rigorous assessment for product quality, efficacy and safety by the Australian Pesticides & Veterinary Medicines Authority (APVMA) and therefore they may carry a greater risk than registered products when used to treat animals. As with all medications, veterinarians must understand and comply with all legal requirements for preparation and use of compounded medications in accordance with national, state and territory control of use and drugs and poisons legislation.

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

A veterinarian may compound a medication without the involvement of a pharmacist. If a pharmacist is involved in the compounding, they are not permitted to dispense an unregistered veterinary medication if a suitable registered medicine is available. The Pharmacy Board of Australia's *Guidelines on Compounding Medicines*[2] specify that medicines may be compounded only if an appropriate registered product is unavailable or unsuitable (for example, if a patient is allergic to an excipient in the registered product); and that a pharmacist should not compound a medicine (whether prescribed or not) that would be a close formulation, and would be expected to produce a similar therapeutic outcome, to an available and suitable registered product.

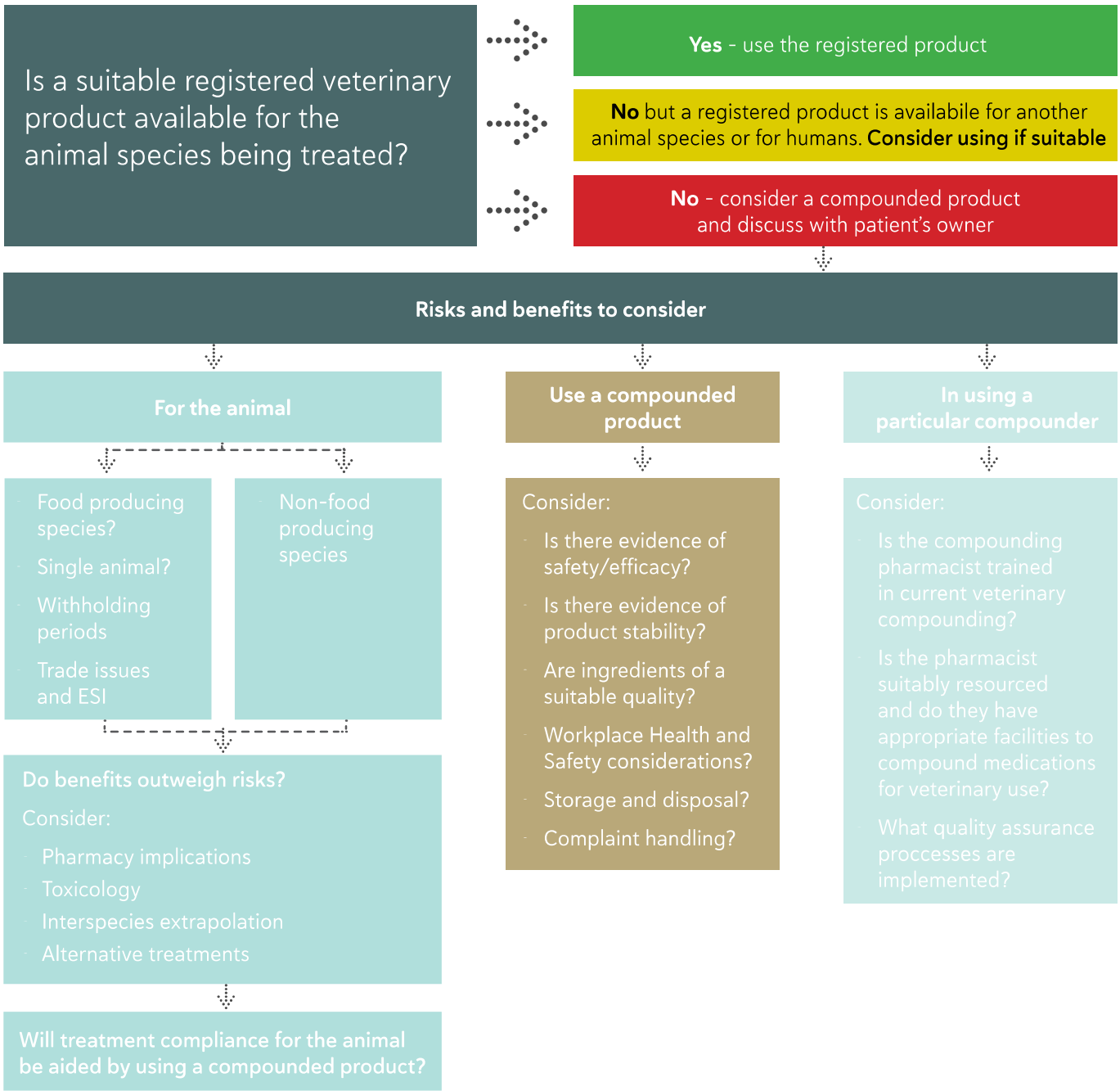
[1] 5 (1) A veterinary chemical product does not include:
(a) a substance or mixture of substances that is:
(i) prepared by a pharmacist in accordance with the instructions of a veterinary surgeon; or
(ii) prepared by a veterinary surgeon; in the course of the practice, by the person preparing the substance or mixture of substances, of his or her profession as permitted by or under a law of this jurisdiction.

[2] https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx Non-compliance with the Pharmacy Board of Australia guidelines by a pharmacist can be result in disciplinary proceedings under national or state/territory law. The guidelines may be used as evidence of what constitutes appropriate professional conduct or practice for pharmacists.

When to use compounded products

All animals deserve the benefit of medicinal products which are suitable for their particular needs. The **decision flow chart** (below) 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 medication where no suitable registered product is available. A medication 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 medication remains with the prescribing veterinary practitioner.

Decision flow chart for use of compounded products by veterinarians



Key questions to ask your compounding pharmacist

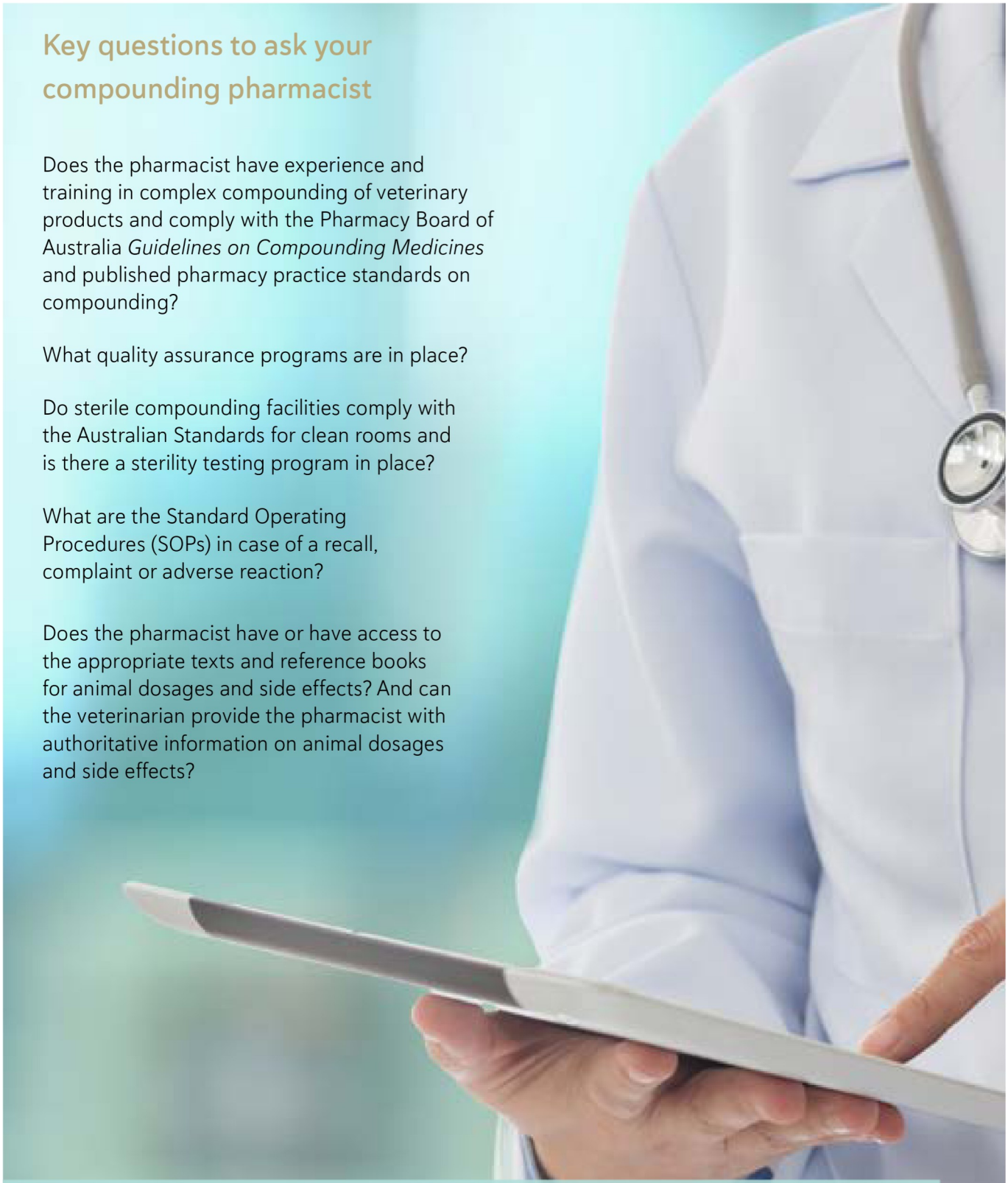
Does the pharmacist have experience and training in complex compounding of veterinary products and comply with the Pharmacy Board of Australia *Guidelines on Compounding Medicines* and published pharmacy practice standards on compounding?

What quality assurance programs are in place?

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

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

Does the pharmacist have or have access to the appropriate texts and reference books for animal dosages and side effects? And can the veterinarian provide the pharmacist with authoritative information on animal dosages and side effects?



Compounded medications 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) and in accordance with all relevant legislation and Pharmacy Board of Australia guidelines.

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

Summary:
Guidelines for the prescription and use of compounded medications

A veterinarian may compound a medication in the course of their practice, and supply that medication to the owner of an animal, for use on that animal under the veterinarian's care.

Pharmacists may compound veterinary medications only on written veterinary instruction or veterinary prescription[3].

A compounded preparation should only be used in circumstances where a registered 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 medications, compounded **medications must be labelled** with all details required on a prescription specific to the animal that is being treated, as required under national, state and territory legislation.

Compounding pharmacists must also comply with relevant legislation and Pharmacy Board of Australia guidelines. The label on any dispensed compounded medication must include details identifying the active constituents, the animal to be treated, instructions for use, the owner, the compounding pharmacist and the prescribing veterinarian. For more information on labelling see section 1 in the FAQs below.

Additional restrictions apply to supply of unregistered veterinary medications for use in **food-producing animals**. A veterinary practitioner may supply or compound a veterinary medication 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. In addition, the pharmacist must exercise their own judgement and must only dispense a medication if it is safe and appropriate to do so. The prescribing veterinarian and/or the compounding pharmacist may be liable for harm, under certain circumstances, 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 medication 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[4] .

Compounded medications should be labelled with an expiry date . The **expiry date**[5] should be based on evidence that the medication will remain physically, chemically and microbiologically stable when stored under the specified storage conditions and during the administration of the medication to the patient. Compounding products are intended for immediate usage and therefore in in most cases the expiry period will be short. No product should be supplied after the expiry date. See also section 4 in the FAQs below.

[3] Note that non-veterinary staff are not permitted to provide instructions (such as a prescription or an order) and that digital signatures are not legal signatures for the purposes of prescribing.

[4] In the Northern Territory, pharmacists may supply by wholesale without a separate wholesaler license - see sections 35 and 57 of the Medicines, Poisons and Therapeutic Goods Act 2012 (NT).

[5] In the case of pharmacists, expiry dates are required under Pharmacy Board of Australia guidelines and pharmacy practice standards.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Questions and answers on prescribing and using compounded medications

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

1.1 The pharmacist must label the compounded medication. A veterinarian may only order a compounded medication on prescription if it is for treatment of a specific animal, which must be identified on the label. Labelling requirements are specified in Appendix L of the Poisons Standard[6] and similar requirements are in state and territory legislation and in guidance to pharmacists. It is good practice to also include the name and address of the prescribing veterinarian or clinic on the pharmacist's label.

1.2 There is some conflict between different regulations as to whether a veterinarian may attach his/her own label to a compounded medication that has been dispensed by a pharmacist. If the veterinarian adds his / her own label, it 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 veterinarian's label. In some states, including NSW, 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 including those in professional practice standards, Pharmacy Board of Australia guidelines, codes, registration standards, state and territory drugs and poisons legislation (see section 16 for a list of this legislation) and premises legislation;
- the *Health Practitioner Regulation National Law Act* (which does not apply to veterinarians), the Agvet Code and Commonwealth Therapeutic Goods legislation; and
- the general law, including tort law (e.g. professional negligence), which applies to all health care professionals.

2.2. Pharmacy Board of Australia Guidelines on Compounding Medicines require that -

- "Pharmacists must meet their obligations outlined in relevant state, territory and Commonwealth legislation as they relate to the preparation, labelling, maintenance of records, storage, dispensing, supply and advertising of compounded medicines.
- Compounded medicines must meet the quality standards set out in the *Therapeutic Goods Act 1989* (Cth). The Board's *Background on the regulation of compounding by pharmacists*[7] information sheet contains information on the requirements of other authorities under their specific legislation, which relate to compounding.
- These [Pharmacy Board of Australia] guidelines must be read in conjunction with:
  - state, territory and Commonwealth legislation relevant to the practice of pharmacy and pharmacy supply of medicines
  - codes and guidelines published by jurisdictional pharmacy premises regulatory authorities about pharmacy premises

[6] the Standard for the Uniform Scheduling of Medicines and Poisons, otherwise known as the 'Poisons Standard' or 'SUSMP' (https://www.tga.gov.au/publication/poisons-standard-susmp)

[7] https://www.pharmacyboard.gov.au/Codes-Guidelines/FAQ.aspx

- the section *Extemporaneous dispensing* in the current edition of the *Australian Pharmaceutical Formulary and Handbook*[8]
- the following practice standards and guidelines:
  - the Pharmaceutical Society of Australia *Professional Practice Standards - Standard 10: Compounding* (also known as *Extemporaneous dispensing*)
  - the Pharmaceutical Society of Australia *Professional Practice Standards - Standard 11: Compounding sterile preparations*
  - The Society of Hospital Pharmacists of Australia *SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments*
  - The Society of Hospital Pharmacists of Australia *SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments*
  - The Society of Hospital Pharmacists of Australia *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments*
  - The Society of Hospital Pharmacists of Australia *SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer*
- occupational, health and safety standards, and
- Australian standards for clean rooms."

2.3. Accordingly, the pharmacy industry is heavily regulated and, like all health care professionals, pharmacists have a professional duty of care to the owners of treated animals. Nevertheless, you should satisfy yourself that a pharmacist is suitably equipped and resourced to compound veterinary medications.

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:

The client has a right to choose

Where a veterinarian writes a prescription for a medication to be compounded, the client may choose which compounding pharmacy to use. A veterinarian may assist their client in this choice, using their knowledge of different pharmacies' ability to compound veterinary medications.

CGMP compliance and quality control

Veterinarians should check whether the compounding pharmacy's facilities and processes comply with the APVMA's Code of Good Manufacturing Practice[9] (CGMP) or the PIC/S Guide to Good Manufacturing Practice[10]. 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) comply with CGMP standards. Pharmacists are not obligated to be CGMP compliant, but pharmacies specialising in compounding should comply with the CGMP or have other quality assurance systems in place.

Veterinarians should also enquire as to whether the compounding pharmacy has evidence of the safety, efficacy and stability of the relevant medication 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;

[8] https://www.psa.org.au/media-publications/australian-pharmaceutical-formulary

[9] https://apvma.gov.au/node/72

[10] https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products

- 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
- 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 specific 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" (or "beyond use") date that should be stated on the pharmacist's label, or on the veterinarian's label if the medication has been compounded by the veterinarian. The expiry period should be based on evidence that the medication will remain physically, chemically and microbiologically stable when stored under the specified storage conditions and during the administration of the medication to the patient. Non-evidence-based 'default expiry periods' should not be used.

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 of this guideline.

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

5.1. 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 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[11].

5.3. In Victoria, for S4 and S8 medications, pharmacists must report to the regulator any requests to dispense requests to dispense more than "appears to be reasonably necessary". However, the Victorian legislation specifically allows that S4 medications may be ordered "in bulk for treatment of flocks or herds of animals"[12].

5.4. The South Australian legislation 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".[13] The legislation does not clearly prescribe the form requirements for such a written order - nevertheless, veterinarians are advised to follow the form requirements for prescriptions when creating such written orders.

[11] Section 12J of the Chemical Usage (Agricultural and Veterinary) Control Act 1988 (QLD).

[12] Regulation 27 of the Drugs, Poisons and Controlled Substances Regulations 2017 (VIC).

[13] Regulation 21 of the Controlled Substances (Poisons) Regulations 2011 (SA).

[14] Regulation 34 of the Controlled Substances (Poisons) Regulations 2011 (SA).

5.5. The New South Wales legislation permits veterinarians to order S4 medications by way of "written orders" (as opposed to prescriptions) where the medication is supplied "for emergency use"[15]. 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. A veterinarian may only order compounded medications on prescription if it is for treatment of a specified, named animal. In general, veterinarians may not order, by way of a prescription, compounded 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. The *Australian Pharmaceutical Formulary and Handbook* (APF) states that pharmacists can compound veterinary medications on a written order, but this must be for a specific patient and the pharmacist must label the medication with the name. As pharmacists need patient details to compound medications, the use of written orders for medications for use in emergency situations generally applies to registered (proprietary) medications, not compounded medications, except where the pharmacist is licensed to sell by wholesale.

6.3. In NSW, the ability of veterinarians to place such written orders (as distinct from prescriptions) is clear (see section 5.5 above). Similarly, for S4 medications, such orders may be permitted in Victoria, Queensland[16], South Australia[17] and the ACT[18] and, if the supply by the pharmacist is considered to be supply by wholesale, the Northern Territory as well[19]. It also appears that such orders are permitted in Tasmania for S3 medications[20] . The position is unclear in Western Australia.

6.4. 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.

6.5. There are few situations where a compounded medication would be required to meet a genuine emergency that could be reasonably anticipated. One possible example would be methylene blue for treatment of nitrate poisoning. This could be supplied by a compounding pharmacist under a written order (not a prescription) for carrying in the equivalent of a doctor's bag for use in emergencies, or it could be compounded by the veterinarian, in compliance with the Agvet Code provisions which allow veterinarians to undertake compounding.

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.

[15] Clause 46 of the Poisons and Therapeutic Goods Regulation 2008 (NSW).

[16] Regulation 200 of the Health (Drugs and Poisons) Regulation 1996 (QLD).

[17] Regulation 21(2)(b) of the Controlled Substances (Poisons) Regulations 2011 (SA).

[18] Regulation 60, 62 and Schedule 1 of the Medicines, Poisons and Therapeutic Goods Regulation 2008 (ACT).

[19] Sections 35 and 57 of the Medicines, Poisons and Therapeutic Goods Act 2012 (NT).

[20] Regulation 53 of the Poisons Regulations 2008 (TAS).

7.2. A pharmacist must label a dispensed compounded medication with the name of the patient to be treated (see section 1.1): this situation can therefore only apply to a compounded medication if it is compounded by the veterinarian.

7.3. However, if this cannot practicably be avoided, then it may be permitted in some states/territories if:

- 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 need not 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 section 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 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. A veterinarian should report any unusual adverse reaction. For registered medicines, the report should be to the APVMA's Adverse Experience Reporting Program and to the company that holds the product registration. Unusual adverse reactions to compounded medications should be reported to and discussed with the compounding pharmacist.

8.3. Both the pharmacist and the veterinarian are professionals who:

- must work to accepted professional standards;
- have 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. No. If the veterinarian marks up the medication, then the pharmacist has supplied by wholesale, which is illegal except by licensed wholesalers. However the veterinarian may charge a fee for writing a prescription, and if applicable a freight fee.

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 situations in which a veterinarian might need to order compounded medications 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 for multiple animals does not necessarily constitute wholesaling. As a general rule, wholesaling is supply where the primary purpose of which is 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"). Supply by a pharmacist to a veterinarian in bulk is wholesaling if the primary purpose of that supply is on-supply by the veterinarian - as distinct from direct administration by the veterinarian to patients. See also section 9.

10.3. Any such supply will need to comply with the quantity limitations discussed in section 5. See section 8 in relation to treating multiple animals from the same container.

11. Can I use price 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, improved palatability or method of administration - or when no appropriate registered product is available. 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 require that the veterinarian should consider other options for treating the animal to avoid the patient animal from suffering unnecessarily or even dying as a result of being left untreated.

11.3. Choosing a compounded medication, supplied by a pharmacist, 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) is not possible: this would breach the obligations of the pharmacist: as explained above, a pharmacist may only compound a medication if an appropriate registered product is unavailable or unsuitable.

11.4. There is an exemption which would apply in the unusual circumstance that the veterinarian is able to compound the medication without using a pharmacist. A veterinarian may compound a medication in the course of their practice, and supply that medication to the owner of an animal, for use on that animal under the veterinarian's care. Such supply, for reasons of price only, 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;
- there are no other treatments that would be satisfactory;
- 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; and
- the veterinarian has the knowledge, competence and equipment to compound the medication.

11.5. In other words, if price is the only reason to choose a compounded medication over an available registered product, the veterinarian may supply a medication compounded by the veterinarian, only after the specific sequence of events described above has taken place.

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. The veterinarian is not required to follow that request and retains his/her professional discretion as to how to treat the patient animal. The veterinarian must be aware that a pharmacist may not compound a medication, or supply a compounded medication, if an appropriate registered product is available and suitable. Although the veterinarian is not bound to follow an owner's 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 these AVA guidelines for use when using compounded medications?

13.1. The AVA guidelines are not binding as a matter of law but they reflect legal requirements and should be held in high regard by veterinarians. Importantly they 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 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 and 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) - or PIC/S for human pharmaceutical products - whereas compounded medications are not subject to the same stringent requirements. Quality may vary between different compounding pharmacies; accordingly, as explained in section 3, a compounder with an effective quality assurance system in place should be preferred.

15.2. Additionally, there may be some lack of awareness surrounding the circumstances in which the use of compounded medication may be appropriate or advantageous. The AVA has sought to address this lack of awareness through the publication of its Guidelines for the preparation and use of compounded pharmaceuticals and this Q&A.

16. What are the laws that control my use of compounded medication that I must be aware of as a veterinarian?

16.1. Veterinarians should be aware of the "control of use" and poisons/therapeutic goods legislation in their respective states/territories, as follows:

New South Wales

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

See also further guidance from NSW Health and the NSW Veterinary Practitioners Board .

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 2017

See also the Victorian Pharmacy Authority Guidelines[23].

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

16.2. Veterinarians should also be aware of:

- the Standard for the Uniform Scheduling of Medicines and Poisons[24] , otherwise known as the 'Poisons Standard' or 'SUSMP';
- the Agricultural and Veterinary Chemicals Code ('the Agvet Code') and Regulations;
- and the veterinary practice legislation and codes of conduct applicable in the jurisdiction in which they are registered.

[21] https://www.health.nsw.gov.au/pharmaceutical/Documents/guide-vetprac.pdf

[22] https://www.vpb.nsw.gov.au/2018-june-compounded-pharmaceuticals

[23] https://www.pharmacy.vic.gov.au/cms_files/News/Victorian%20Pharmacy%20Authority%20Guidelines%20effective%201%20Nov%202018.pdf

[24] https://www.tga.gov.au/publication/poisons-standard-susmp

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

As explained earlier (section 1.1), a pharmacist must label a compounded medication with the name of the patient to be treated: this scenario can therefore only apply when the compounded medication is compounded by the veterinarian. 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 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.

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