Exposure Draft: NSW Medicines, Poisons and Therapeutic Goods Regulation 2023

Submission of the
Australian Veterinary Association Ltd
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The Australian Veterinary Association (AVA)

The Australian Veterinary Association (AVA) is the peak professional association representing veterinarians in Australia.

Our members come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, livestock, and wildlife. Government veterinarians work with our animal health, public health, and quarantine systems while other members work in industry, research, and teaching. Veterinary students are also members of the Association.

We empower the veterinary profession to thrive by providing a voice, education, community, and support.

Discussion

The AVA thanks the NSW Ministry of Health for the opportunity to offer feedback on the exposure draft of the NSW Medicines, Poisons and Therapeutic Goods (MPTG) Regulation 2023. However, it is with significant concern that we address the potential adverse effects and unintended consequences the proposed regulation in its current iteration would impose on veterinary practitioners and the animals that they treat.

Particularly disconcerting is the observation, as noted on page 113 of the Regulatory Impact Statement (RIS), that the list of consulted stakeholders during the regulation's development did not include representatives from veterinary practice, especially the veterinary peak body the AVA. This exclusion of veterinary practice expertise and representation in the RIS's development has unfortunately led to a number of unintended and detrimental consequences associated with the proposed regulation.

Please note, the AVA has several polices, guidelines, and recent submissions relating to MPTG that are highly relevant to the MoH for the amendment to the proposed MPTG regulation 2023:

- AVA Policy – Veterinary prescribing rights
- AVA Policy – Veterinary use of compounded pharmaceuticals
- AVA Policy – Responsible use of veterinary medicines on farms
- AVA Policy – Code of practice for the use of prescription animal remedies (schedule 4 substances) in the poultry industry
- AVA Policy – Use of medicinal cannabis in animals
- AVA Policy – Cytotoxic Drug Safety
- AVA Guidelines – Cytotoxic Drug Safety
- AVA Guidelines – For Prescribing, Authorising and Dispensing Veterinary Medicines
- AVA Guidelines – For the preparation and use of compounded pharmaceuticals
- AVA response to the national review of the guidelines for compounding of medicines
- AVA response to the Independent review of the Agvet chemical regulatory framework

Furthermore, we recommend the MoH review the following documents from the Australian Pesticides and Veterinary Medicines Authority (APVMA):

- Australian code of Good Manufacturing Practice (cGMP) for veterinary chemical products,
- Manufacturers' Licensing Scheme, and
- the Agricultural and Veterinary Chemicals (Manufacturing Principles) Determination 2014 that defines the principles that manufacturers of veterinary chemical products must comply with to obtain and retain a manufacturing licence.

An addendum has been included at the end of this submission to provide MoH with background and insights of the veterinary profession and veterinary medicine. The addendum aims to highlight

the need for clear guidance in the MPTG regulation, specifically tailored to the unique requirements of veterinary medicine, ensuring effective care while safeguarding animal health and welfare.

In this submission, we aim to provide comprehensive feedback, highlighting critical issues within the proposed regulation. We also propose necessary amendments and additions and offer a broader perspective on the MPTG framework as it pertains to veterinary practice in NSW. There are in particular seven important key issues within the proposed regulations (Sections 11, 35, 38, 77(2), 79(1), 109, and 152) that require amendment to reflect the current high standards of veterinary practice.

Proposed Section 6: Veterinary practitioners and etorphine—the Act, s 6

For this regulation, etorphine is taken to be a Schedule 8 substance, and not a Schedule 9 substance, when obtained or supplied by a veterinary practitioner in accordance with an authority for etorphine granted by the Health Secretary under section 23 or 36.

The AVA are supportive of this proposed section as it identifies the diversity of species that veterinary practitioners must treat.

Proposed Section 11: Wholesale supply by pharmacists to authorised practitioners

(1) For the Act, section 14(a), wholesale supply of a Schedule 4 or 8 substance by a pharmacist to an authorised practitioner for emergency use is authorised if the supply is in accordance with a written order of the authorised practitioner.
(2) This section does not apply to the following Schedule 4 or 8 substances—
(a) for all authorised practitioners—a Schedule 4 or 8 substance that is not a registered good, and
(b) for a veterinary practitioner—a Schedule 4 or 8 substance that is not registered under the Commonwealth Agvet Codes.
(3) The pharmacist must keep a record of Schedule 4 or 8 substances wholesale supplied under this section.
Maximum penalty—Tier 6 penalty.

Within the current regulation pharmacies are allowed to wholesale supply in a very limited number of circumstances, including – Wholesale supply to an authorised practitioner for the purposes of an emergency supply or emergency supply by a veterinary practitioner.
The problem with this proposed section 11 if adopted as-is, is that it will result in veterinarians no longer having compounded emergency medicines on the shelf of their practice. This will have significant adverse impacts on animal health and welfare as well as public health.

The AVA Guidelines for the preparation and use of compounded pharmaceuticals advises that it is best practice that a compounded product is only used when no other registered product can effectively treat the condition. A compounded medication should only be used if the registered product is unavailable or unsuitable. In many cases in veterinary practice, it is necessary to have compounded products available for emergency use.

Veterinarians need to be able to have a mechanism to be able to access compounded medications. Particularly medications that are becoming commonly used in other countries for animal health and are found to significantly improve health and welfare outcomes. A current example is the use of trazodone, a serotonin antagonist/reuptake inhibitor (SARI) with anxiolytic activity, that is effective in reducing anxiety and fearfulness in highly stressed animals, thus improving animal welfare and the welfare and safety of veterinarians and their staff. If veterinarians don't have the ability to have access to compounded drugs for emergency use, effective treatments would become unavailable for those patients and public health as well as animal health and welfare will be seriously compromised.

While the AVA appreciates the efforts to regulate the wholesale supply of medicines, it is crucial that the unique needs and practices of veterinary medicine are taken into account to avoid detrimental impacts on animal health and welfare.

We understand the argument that compounded drugs are not held to the same standards as other registered products. However, a number of veterinary medicines are considered essential for emergency use and are not available as registered products. There is a risk analysis undertaken by veterinarians before every medication is given and in some cases the benefit of using a compound drug outweighs the risks of not using a drug at all.

The AVA acknowledges the intent of Proposed Section 11 regarding the wholesale supply by pharmacists to authorised practitioners. However, we raise significant concerns about the implications of this section on veterinary practices, particularly in emergency situations. These concerns include:

- As it stands, the proposed section restricts veterinarians from obtaining compounded emergency medicines. This limitation could severely impact animal welfare, as veterinarians often rely on these medicines for timely and effective treatment.
- The current RIS focuses on human applications in the proposed restrictions on S8 drug compounding, but it overlooks the unique needs of veterinary medicine. This oversight will lead to unintended consequences in veterinary settings, especially in the treatment of small, large, or exotic animals, where precise dosing and specific formulations are crucial.
- A number of essential veterinary medicines, crucial for emergency use, are not available as registered products. The concern about product quality in compounded medicines can be addressed by ensuring that compounding is performed under a quality assurance program.

We note the RIS reports they received correspondence from the Veterinary Practitioners Board (VPB) of NSW noting that they do not support supply by wholesale to veterinarians of compounded medicine for emergency use. The VPB commented *"that batch preparations of compounded products are not subject to the rigorous testing for quality, safety, stability and efficacy that applies to registered products and therefore pose a greater risk to animal health and welfare if made available to multiple animals by wholesale."* However, the AVA argues that if a quality program is in place, then the concern of poor quality leading to adverse outcomes will be mitigated.

The AVA strongly recommends amending the proposed MPTG regulation Section 11 to include an exception for pharmacies complying with the Australian Pesticides and Veterinary Medicines Authority (APVMA) code of Good Manufacturing Practice (cGMP), as verified by an independent GMP auditor. This amendment will ensure that veterinarians continue to have access to essential compounded medications without compromising the quality of these products.

Additionally, supporting recommendations consistent with AVA proposed changes, the AVA suggest the MoH review the 2021 final report from the Independent review of the pesticides and veterinary medicines regulatory systems in Australia that included the following recommendations:

> *31 Recommendation: The Panel recommends that compounded veterinary products fall within the scope of the future regulatory system but are exempt from registration where they comply with the prescription protocol. In developing the protocol, the Panel recommends:*
> - *registered products be considered first, and compounded products are only prescribed where no suitable or available regulatory assessed products exist*
> - *the prescription protocol is finalised and implemented under the single national law for control-of-use*
> - *the APVMA works with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies to ensure one or more suitable manufacturing standards are established to enable said exemption.*
>
> *32 Recommendation: The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good*

compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.

Proposed Section 35: Restriction on non-wholesale supply of certain Schedule 4 and 8 substances

(2) A veterinary practitioner must not non-wholesale supply the following—
(a) a compounded Schedule 4D substance for non-topical use,
(b) a compounded Schedule 8 substance,
(c) dexamfetamine or lisdexamfetamine,
(d) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine.
Maximum penalty—Tier 6 penalty

The nature of veterinary practice is unpredictable by providing care to a wide range of animals with varying medication and dosage needs. For example, veterinarians may treat companion animals, large animals, wildlife, birds and exotics. There are numerous species for which suitable registered drugs are not available to meet their treatment needs, and as a result, several types of veterinary practice (eg bird medicine, exotics) are heavily reliant on compounded medicines in their daily practice. This proposed regulatory provision could delay access and compromise patient care, and as a result, animal welfare.

The AVA is concerned the Regulatory Impact Statement (RIS) for the proposed regulation listed examples of scheduled 4D substances which are focused on human impacts and are not applicable for veterinary uses. It remains unclear to the veterinary profession the rationale and intention for this section.

Whilst the AVA understand the MoH is trying to address the problem of diversion of S8 substances to criminal supply, the proposed changes will be impractical for veterinary practice.

This proposed change will impact the way veterinarians treat animals and the MoH needs greater understanding of the potential unintended consequences the proposed regulation will have on veterinary practice.

The AVA recommends the MoH seek a balance between increased oversight of veterinary practice and best practice for veterinarians. The NSW Veterinary Practitioners Board conduct hospital inspections, review of clinical records and S8 record keeping, this should sufficiently identify compliance with appropriate use or reveal diversion for further investigation.

Proposed Section 38: Restriction on issue of prescriptions for certain Schedule 4 and 8 substances

(2) A veterinary practitioner must not issue a prescription for the following—
(a) a compounded Schedule 4D substance for non-topical use,
(b) a compounded Schedule 8 substance,
(c) dexamfetamine, lisdexamfetamine or methylphenidate,
(d) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine.
...
(4) Subsections (1) and (2)(a) and (b) do not apply to a person who issues the prescription in accordance with an approval or approval exemption.

A number of Schedule 4D products may be needed as compounded products when registered products are not suitable or available. For example, diazepam, doxapram or pregabalin may be needed clinically and available only by prescription for a compounded product in an appropriate formulation for an animal patient.

In addition, especially for unusual or exotic pets of low bodyweight where very low doses are indicated (eg birds, reptiles) or a large animal requiring high dosage, it may be necessary to

compound a Schedule 8 product for use in pain management or sedation. There are numerous species for which suitable registered drugs are not available to meet their treatment needs, and as a result, many types of veterinary practice (eg bird medicine, exotics) are heavily reliant on compounded medicines.

Restricting access this way in the proposed regulation will result in poor animal health and welfare outcomes.

Proposed Section 77 (2): Approvals required for activities involving Schedule 8 substances—the Act, s 69(1)

(2) A veterinary practitioner must not supply, administer or issue a prescription for a compounded Schedule 8 substance without an approval.

As in section 38 above and especially for unusual or exotic animals of low bodyweight where very low doses are indicated, or a large animal requiring high dosage, it may be necessary to compound a Schedule 8 product for use in pain management or sedation.

Proposed Section 79 (1): Compounding of Schedule 4D and 8 substances

(1) For the Act, section 55(1), a medical practitioner, dentist or veterinary practitioner must not compound a Schedule 4D substance for non-topical use or a Schedule 8 substance unless the person is acting in accordance with an authority granted by the Health Secretary under section 80.
Maximum penalty—Tier 6 penalty

Schedule 8 products commonly used by veterinarians include buprenorphine, butorphanol, ketamine, methadone, and morphine.

Frequently veterinarians will combine a schedule 8 substance with one or more other constituents, or manipulate a commercial product (for example, dilute the product to ensure more accurate dosing). For example, ahead of surgery, multiple sedative, analgesic, or anxiolytic medications will be combined into a single syringe to be administered as an intramuscular or subcutaneous injection. Administering these injections separately causes pain and distress to animal patients, and increases the risk of harm to veterinary staff. Additionally, when patients require ongoing analgesia while hospitalised, a combination of medications, including S8s will be mixed in a single bag to ensure accurate and safe dosing when administered as an infusion. The combination of methadone, lignocaine and ketamine is a commonly used formulation in treatment of veterinary patients.

The AVA are concerned the proposed regulation for compounding would exclude veterinarians' ability to reconstitute or manipulate commercial products that may require the mixing of one or more ingredients, without a specific authority from the Health Secretary that is usually provided for a single patient.

The AVA recommends veterinarians be exempt from section 79(1) in the proposed regulation.

Proposed Section 95, 96 & 97: Persons responsible for drug registers, Drug registers for Schedule 8 substances and Entries in drug registers for Schedule 8 substances

95 Persons responsible for drug registers
(1) In this part, the ***responsible person*** *for each relevant place is as follows—*
(i) for a veterinary hospital—the holder of the veterinary hospital licence under the Veterinary Practice Act 2003,

96 Drug registers for Schedule 8 substances

(1) A responsible person for a relevant place at which a Schedule 8 substance is kept must ensure a drug register is kept in accordance with this part.
Maximum penalty—Tier 6 penalty.
(2) A drug register must be kept—
(a) in the form of a book that—
(i) contains consecutively numbered pages, and
(ii) is bound so the pages cannot be removed or replaced without trace, and
(iii) specifies the particulars required to be entered under section 97(1), or
(b) in an approved electronic form.
(3) A separate page of a drug register in the form of a book, as referred to in subsection (2)(a), must be used for each Schedule 8 substance and for each form and strength of the Schedule 8 substance.
(4) Despite subsection (3), a separate page is not required for records of destruction of each Schedule 8 substance.

97 Entries in drug registers for Schedule 8 substances
(1) On the day on which a person manufactures, receives, supplies, administers or uses a Schedule 8 substance at a relevant place, the person must enter the following in the drug register at the relevant place—
(a) the quantity of the Schedule 8 substance manufactured, received, supplied, administered or used,
(b) the name and street address of the person to, from or by whom the Schedule 8 substance was manufactured, received, supplied, administered or used,
(c) for a Schedule 8 substance supplied or administered to an individual—the name of the person—
(i) who supplied or administered the substance, or
(ii) under whose direction or direct personal supervision the substance was supplied or administered,
(d) for a Schedule 8 substance supplied or administered on prescription—
(i) the reference number for the prescription, and
(ii) the name of the person who issued the prescription,
....
(i) for a Schedule 8 substance administered to an animal or supplied for the treatment of an animal—the species and owner's name and street address,
(j) for a Schedule 8 substance administered to an animal—the name of the veterinary practitioner—
(i) who administered the substance, or
(ii) under whose direction or direct personal supervision the substance was administered,
(k) the actual quantity of Schedule 8 substances of the same kind that remains at the relevant place after the event,
(l) other approved information.
(2) The person making the entry in the drug register must sign and date each entry.

Proposed section 95 specifies a person responsible for a drug register in a 'veterinary hospital'. However, this raises a concern regarding its applicability to veterinary practices that do not fall under the classification of a hospital. How would these requirements translate to smaller or differently classified veterinary practices? This distinction is crucial for ensuring that all veterinary establishments, regardless of their size or classification, are adequately covered by the regulation and can adhere to its guidelines effectively.

The AVA supports maintenance of a register for schedule 8 drugs as a fundamental tenet of controlling misuse of restricted drugs. The AVA Guidelines for Prescribing, Authorising and Dispensing Veterinary Medicines states for schedule 8 drug 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.

However, we urge the MoH to also consider how these increased recording requirements will impact veterinary practice for increased administrative burdens and increased recording requirements that may impede prompt access during animal euthanasia and emergencies, and be thus problematic from an animal welfare perspective.

Proposed Section 109: Storage requirements for Schedule 8 substances in other places

(1) A person in possession of a Schedule 8 substance to which section 107 or 108 does not apply must ensure the Schedule 8 substance is stored in accordance with this section.
Maximum penalty—Tier 6 penalty.
(2) The substance must be stored—
(a) apart from all other goods, and
(b) in a dedicated room or receptacle.
(3) The dedicated room or receptacle must be kept securely locked when not in immediate use.
(4) A receptacle must—
(a) be securely attached to a part of the premises, and
(b) not be accessible by members of the public.
(5) Storage must comply with the medication storage standards, including in relation to the receptacle.
(6) An authorised practitioner or a paramedic complies with this section by keeping a substance, kept for emergency use, in a bag that is in a room or a vehicle that is kept locked when not occupied by the person.
(7) This section does not apply to a person in possession of a Schedule 8 substance if the substance was lawfully supplied to the person from an authorised practitioner or pharmacist.

Currently, the S4D product pentobarbitone is required to be stored in a locked receptacle, and it is practical for veterinarians to keep it in the S8 safe. The proposed section 109 would require storage of Schedule 8 substances separately from the locked storage of pentobarbitone. This impractical proposed regulation would impose an additional burden on veterinary practices, without an additional benefit to patients or the public.

AVA proposes that S4D and Schedule 8 substances be allowed to be stored together in the same secure receptacle or safe. We recommend this regulation provide an exemption for veterinary practices and for the MoH to provide guidance to veterinarians on the allowed ways to store pentobarbitone with other S8 substances in veterinary practices and vehicles.

Proposed Section 152: Sterile compounded preparations—the Act, s 55

(1) A person compounding a sterile compounded preparation must comply with the requirements specified in Compounded medicines and good manufacturing practice (GMP), Guide to the interpretation of the PIC/S Guide to GMP for compounded medicinal products, published by the Therapeutic Goods Administration.
Maximum penalty—Tier 6 penalty.
(2) This section does not apply to a person compounding a substance—
(a) at a public health entity, for the purposes of the treatment of a patient at the public health entity, or
(b) at a private health facility, for the purposes of the treatment of a patient at the private health facility.

(3) A reference to a private health facility in subsection (2)(b) does not include a pharmacy at a private health facility.
(4) In this section— sterile compounded preparation has the same meaning as in the Act, section 55.

Veterinarians are often required to compound parenteral or ophthalmic use medicines (dilutions, manipulation) for the treatment of their patients. Regularly these products are needed for immediate use and could be prepared for an individual patient or a flock/herd of animals. For example:

- Treatment with cyclosporin at point of care compounding for keratoconjunctivitis sicca in dogs.
- Gentamicin may be compounded for ocular administration to horses for the treatment of keratitis.
- Blood products are compounded for parenteral or ocular use by veterinarians for the treatment of several serious conditions, both for transfusion medicine and in the treatment of corneal disease.
- Ceftazidime is one of the only injectable antibiotics appropriate for treating reptile patients, and this is required to be diluted to ensure appropriate dosing for low body-weight patient.

This proposed regulation will require in-practice sterile compounding of products for injection or for ophthalmic use to be undertaken in compliance with the TGA code of Good Manufacturing Practice – a standard that no veterinary practice and most animal health companies do not (and unlikely could) comply with.

The AVA is seeking exemption of veterinarians compounding a substance for injection or ophthalmic use during the treatment of an animal patient. The AVA suggests adding an exemption clause to subsection (2) for example: (2)(c) This section does not apply to a person compounding a substance during the treatment of an animal patient by a veterinarian.

We acknowledge the concerns of the MoH regarding safeguards for animal safety. It is important to emphasise that the Veterinary Practice Act schedule 2 veterinary practitioners code of professional conduct, along with the NSW veterinary oath, provides a robust framework ensuring that veterinarians uphold their ethical and professional responsibilities. These obligations are centred on practicing veterinary science with integrity and conscientiousness, prioritising the welfare of animals, as well as the health of both animals and humans, and contributing positively to the community. This framework not only guides but also mandates veterinarians to adhere to the highest standards of care and ethical practice, thereby safeguarding animal safety effectively.

Additionally, this section further highlights the need for the AVA's earlier recommendation for section 11 to include an exception for pharmacies adhering to the Australian Pesticides and Veterinary Medicines Authority (APVMA) code of Good Manufacturing Practice (cGMP).

Veterinarians may require a compounded sterile preparation for ophthalmic or parenteral use that they cannot prepare from available registered products and therefore need to provide instructions and a prescription to a pharmacist to compound the sterile veterinary medicines. Section 1 of proposed Section 152 will not allow compounding of a single unit for a single patient. As this is a low risk situation (ie only one patient being treated), an exception is appropriate and consistent with the need to manage risks. For example, the exception could be for a person compounding a sterile preparation for use in a single patient, provided the method of sterile preparation is in compliance with an acceptable code of practice (for example, the USP monograph on sterile manufacture).

Proposed Section 153: Pentobarbital for use in animals—the Act, ss 55 and 150

(1) This section applies to pentobarbital obtained or used by a nominated person for the destruction of an animal.

Of Note, The AVA discussed section 153 with the MoH seeking clarification for the purposes of this regulation if a veterinarian was considered a *nominated person.* Whilst, the MoH have confirmed that there is no proposal to limit the ability for veterinarians to administer pentobarbital beyond current practice, greater clarity in the regulation is requested.

Veterinarian expertise on the NSW Advisory Group

The *Medicines, Poisons and Therapeutic Goods Act 2022, section 127* provides the statutory arrangements for the MPTG Regulatory Advisory Committee. The lack of veterinary considerations in the development of this draft regulation and the detrimental impacts it would have on veterinary practice, highlights the essential need for the official rather than optional appointment of veterinary representation to the committee. As highlighted in the extract below.

Medicines, Poisons and Therapeutic Goods Act 2022, section ***127, Regulatory Advisory Committee***
(5) The Health Secretary must appoint the following—
(a) a person nominated by the Commissioner of Police,
(b) a person nominated by SafeWork NSW,
(c) a person nominated by the Australian Medical Association,
(d) a person nominated by the New South Wales branch of the Pharmacy Guild of Australia,
(e) a person nominated by the New South Wales branch of the Pharmaceutical Society of Australia.
(6) The Health Secretary may appoint persons who the Health Secretary considers have qualifications or experience in the following areas—
(a) medical, dental, nursing and midwifery,
(b) veterinary practice,
(c) industrial use of scheduled substances, including in primary industry,
(d) pharmacology,
(e) toxicology,
(f) the medicines manufacturing and distribution industries,
(g) the development of medicines and the regulation of scheduled substances, including their registration as therapeutic goods under the Commonwealth Therapeutic Goods Act,
(h) assessing the risk of harm to humans, animals or the environment arising in connection with therapeutic goods,
(i) as a consumer of therapeutic goods.

We note there currently is a veterinary representative on the committee as an observer. However, there is a clear need for a veterinarian to be officially appointed to the Regulatory Advisory Committee to provide representation on veterinary matters.

As with the provisions in clauses 127 (5) (c, d, and e), the veterinary representatives should be nominated by the AVA to ensure the representative through the AVA can consult broadly with the veterinary profession on a range of issues, rather than a regulatory veterinary representative.

General comments and definition of compounding

The AVA strongly urges the MoH to consider incorporating the AVA guidelines for the preparation and use of compounded pharmaceuticals into their review and subsequent amendment of the draft MPTG regulation. These comprehensive and informative guidelines have been meticulously developed to aid veterinarians in making well-informed decisions regarding the use of compounded medications in veterinary practice. By referencing these guidelines, regulators can gain a deeper understanding of the accepted best practices in compounding for veterinary purposes, thereby ensuring that regulations align with the highest standards of veterinary care and compounded medication safety.

The current NSW Medicines, Poisons and Therapeutic Goods Act and its accompanying draft MPTG regulations would benefit from the inclusion of a clear definition of 'compounding.' Such a definition would provide essential clarity and foster a better understanding of the MPTG's intentions regarding regulating compounding practices.

It is recommended to consider the standard definition provided by the Therapeutic Goods Administration (TGA) that defines compounding as: *The preparation, mixing, assembling, altering, packaging, and labelling of a medicines, medicine-delivery device or device in accordance with a doctor's prescription, or initiative based on the doctor/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:*

- *Preparation of medicine dosage forms for both human and animal patients*
- *Preparation of medicines or devices in anticipation of prescription medicine orders based on routine, regularly observed prescribing patterns*
- *Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients*
- *Preparation of medicines or devices for the purposes of, or as an incident or, research (clinical or academic), teaching, or chemical analysis*
- *Preparation of medicines and devices for a doctor's premises use where permitted by Commonwealth and State law.*
- *Synthesis of a radiopharmaceutical medicine, e.g. radiolabelling of a ligand with a radioisotope.*

Although this TGA definition is oriented towards human treatment, it could be adapted and expanded to encompass all authorised prescribers, including those in veterinary medicine. Integrating such a comprehensive definition into the MPTG regulations would not only align with national practices but also ensure a uniform understanding across all medical fields, ultimately benefiting both human and animal health.

Draft MPTG Regulation Impacts on Veterinarians in Research

As per the AVA previous recommendations for section 79(1) in the proposed regulation seeking veterinarians to be exempt from restrictions to compound Schedule 4D and 8 substances. We extend this recommended exemption also for veterinarians in research settings to compound medicines without the need to seek additional authority and not strictly follow the TGA GMP guide. This change acknowledges the practicalities of veterinary research, where aseptic techniques and many GMP principles are already in practice, especially when dealing with compounded drugs necessary for laboratory animals. The rationale behind this recommendation is to reduce the administrative burden on veterinarians in research, who are already skilled in safe drug handling and operate under the oversight of an Animal Ethics Committee. The proposed changes aim to address practical challenges in veterinary research without compromising animal welfare or research integrity. These changes would streamline processes, make drug access more efficient for veterinarians, and ultimately benefit research progress.

The AVA is concerned the proposed process of obtaining separate approval from DMT authorities for drugs in animal research for each research project is burdensome, particularly for small teams handling multiple projects. The AVA recommends simplifying this by allowing veterinarians to use their professional veterinary registration to utilise S2-S8 substances in research without the need to seek additional approvals from the DMT authorities. This would streamline the process and reduce administrative load, covering both research activities and clinical treatment of animals in research.

Additionally, the AVA notes the draft MPTG regulation currently lacks a clear definition of "treatment of an animal", thus leading to ambiguity and potential misinterpretation, particularly for veterinarians writing prescriptions for animals in research. The AVA request the MoH provide clarification to veterinarians on when scripts are permitted, either through the new MPTG

regulation or the Guide to the MPTG legislation for veterinary practitioners when it is updated. It is suggested that scripts are only permitted when a veterinarian has clinically assessed an animal and deems medication is necessary for their condition. This would clarify the definition of 'treatment of an animal' which necessarily requires clinical assessment and treatment for recovery which is not the situation in animal research.

Prescriptions

Prescriptions provided by veterinarians are often provided to pet owners to be used with online pharmacies. As per regulations, these pharmacies are required to receive a physical copy of the prescription. There have been anecdotal reports of fraudulent prescriptions, copied prescriptions, and delays in pharmacies requesting original prescriptions, sometimes after dispensing repeats.

The AVA would welcome NSW health exploring the landscape of online veterinary pharmaceuticals and investigate ways to ensure the validity of prescriptions to the benefit of patients, animal owners, and practitioners alike.

Contact

Liz Gemes
Senior Advocacy Officer
Australian Veterinary Association
E: Liz.Gemes@ava.com.au T: (02) 9431 5050

Addendum – Background on Veterinary Medicines for the NSW Ministry of Health

VETERINARY MEDICINES - THE GROWING NEED

INTRODUCTION

Veterinary practitioners are well qualified professionals whose practice of veterinary medicine is at a standard that meets and exceeds the expectations of their clients (AVBC 2023). This increasingly requires access to veterinary medicines of suitable quality, safety, and effectiveness and with a suitable dosage form for use in a number of species, as, when the product cannot be administered, it cannot be effective. The veterinary profession relies on the veterinary medicine regulatory system (especially the Australian Pesticides and Veterinary Medicines Authority - APVMA) to facilitate access to needed medicines of appropriate quality. However, for many species, especially captive or wild mammals, birds, reptiles and invertebrates, there are few if any suitable registered veterinary medicines available to meet the growing needs of animal health and welfare. The Australian veterinary profession is regarded highly by its global counterparts. In a country with a significant livestock population together with growing importance of companion and myriad other animal species, veterinarians fulfill an essential role in supporting animal health and welfare.

THE CURRENT SITUATION

Training and Qualification of Veterinarians

Australian veterinarians of today and the future complete a demanding and intensive period of study to gain the degrees of Batchelor of Veterinary Science or Doctor of Veterinary Medicine (DVM). The comprehensive study provides veterinarians with the competencies to participate in a profession that can attend to the health and welfare of all non-human animal species. Core subjects of the extensive DVM syllabus include anatomy, physiology, pharmacology, microbiology, parasitology and the multiple constituents of veterinary medicine and veterinary surgery. Knowledge and experience of these subjects provide a solid foundation for the diagnosis of physiological and pathological abnormalities and development of therapeutic plans that include the selection and use of the most appropriate veterinary medicines.

Veterinary Professionalism

Professionalism has been defined as "…a combination of knowledge, skills, trustworthiness and altruism found in those who commit themselves to a life of service to others" (Beaton 2010).

Vandeweerd et al (2012) emphasised that the veterinary profession "has the ethical obligation to provide effective and safe treatments and recommendations in a rapidly changing market with both more price-conscious clients and a more demanding regulatory environment. Careful decisions are required to minimise potential liability risks."

In a commentary on the future of the professions, Susskind and Susskind (2015) summarised society's view of professions by noting that "in acknowledgement of and in return for their expertise, experience and judgement, which they are expected to apply in delivering affordable, accessible, up-to-date, reassuring and reliable services, and on the understanding that they will curate and update their knowledge, and methods, train their members, set and enforce standards for the quality of their work, and that they will only admit appropriately qualified individuals into their ranks, and that they will always act honestly, in good faith, putting the interests of clients ahead of their own, we (society) place our trust in the professions in granting them exclusivity over a wide range of socially significant services and activities, by paying them a fair wage, by conferring upon them independence, autonomy, rights of self-determination and by according them respect and status".

Clearly veterinarians, as professionals, have demanding responsibilities which when performed with skill and aptitude can earn the trust of society. It is maintaining this trust that provides the veterinary profession with a social licence to continue their work. Trust can be undermined and lost readily, and veterinarians understand that every action is scrutinised and must be undertaken to the highest standards.

The clients of veterinarians, and society as a whole, expect veterinarians to select and use the most appropriate veterinary medicines available. Veterinarians in turn rely on the expertise of the regulator of veterinary medicines to assess new medicines thoroughly before registration. Veterinarians rely on the label of registered products to provide essential information on the indications for the medicine, the dosage regimen and the precautions that must be observed. This is a fundamental role of the regulator, as products that do not perform as expected, especially those that are ineffective for the label indication, can seriously and irreversibly effect the health and welfare of treated animals. However, not all medicines required by veterinarians to support the health and welfare of veterinary patients are available as registered veterinary medicines, or in formulations suited to individual animal patients.

Animals under the care of the veterinary profession

The veterinary profession is becoming increasingly focused on the needs of its clientele. For both production (food and fibre production) animal and non-production animal species practice there is a growing expectation for precision of diagnosis and treatment with an emphasis on preventive interventions. Similarly, there are expectations for a similar sophisticated and continuously refined approach to the health and welfare of wildlife, unusual pets, and zoo animals. While cattle (dairy and beef), sheep (wool and meat), pigs (meat) and poultry (meat and eggs) dominate food animal practice, there are many other less numerous production animal species to consider, including goats, alpacas, camels (milk and meat), rabbits, kangaroos, crocodiles, game birds, bees and aquaculture species. Each species, irrespective of its numbers, has its own requirements for veterinary professional intervention and unique needs for veterinary medicines. Indeed, for some livestock industries, the activities of many practitioners (e.g. pig, poultry, sheep, feedlot) are directed almost exclusively towards flock/herd health, the prevention of disease and the stewardship of veterinary medicine use, rather than traditional single animal clinical medicine. Veterinarians engaged in such practice have developed considerable expertise relevant to the management of risks associated with the use of veterinary medicines.

According to a recent survey (Animal Medicines Australia and Newgate Research, 2022) veterinarians in small animal practice are available to attend to the needs of an estimated 6.4 million dogs, 5.3 million cats, 11.3 million fish, 3.9 million birds, 901,000 small mammals, 538,000 reptiles and 378,000 'other' pets. The relationship between owner and pet is extraordinarily important. The survey reported that "pets are seen as sources of unconditional love and joy, with many treated as life companions, best friends and family members. Indeed, many pet owners enthusiastically extolled the benefits of ownership, with some saying they cannot imagine life without their pets. Beyond love and companionship, owners are also quick to mention pets' positive impacts on their physical and mental health." Clearly there exists an extraordinary need for veterinarians to have access to high quality veterinary medicines to support the health and welfare needs of companion animals.

Access to high quality veterinary medicines

There is an important distinction between production animal medicine and the medicine of all other animal species.

Production animals, producing food (meat, milk, eggs, honey) and fibre (wool, cashmere, mohair, alpaca fleece and other fibres), are raised to meet specific food safety, health, welfare, trade and other standards. As a consequence of these production standards, the number and type of medicines available to support the health and welfare of individual animals and groups of animals is

very limited and not expected to change in the future. A significant consideration is that of residues (meat, wool etc) following treatment and the need to ensure that maximum residue limits (MRLs) are not exceeded, often requiring the need for a withholding period (WHP). When an MRL is not available or when products are used in a way other than described on the label (extra-label use or ELU), veterinarians must determine and recommend a WHP that prevents the MRL from being exceeded to ensure that produce is safe and meets the stringent standards applied domestically and by trading partners.

For companion animal and other non-production animal species, however, veterinarians are currently permitted to use veterinary medicines registered by the APVMA as well as veterinary medicines acquired from other sources, for example products registered by the TGA for use in humans. The need for an increasing formulary of veterinary medicines is driven by an increasing number of species presenting for veterinary attention and the significant role played by animals in the lives of their owners. There is an expanding number of health and welfare problems requiring treatment, often for extended periods, even for the entire remaining lifetime of the animal being treated. Infectious and non-infectious diseases are treated. Endocrine disorders such as hyperadrenocorticism, diabetes and hyperthyroidism; a diverse array of cancers; heart disease, skin disease; epilepsy and other CNS disorders; reproductive disorders; urinary tract disorders, musculoskeletal problems, notably osteoarthritis; ophthalmological and otological disorders – all increasingly demand attention and a high standard of management. Infectious and parasitic diseases may not necessarily manifest consistently or as classical disease but increasingly require veterinary investigation and treatment. The possibility of the emergence, or new manifestations, of disease due to prokaryotic (bacterial and viral) and eukaryotic (protozoal and fungal) pathogens, frequently associated with environmental or husbandry changes, cannot be reasonably anticipated by a registration system and the veterinary profession provides the essential function that ensures that productivity, animal health and welfare are adequately protected in such circumstances.

Ideally, all veterinary medicines are subject to the rigorous quality, safety, and efficacy requirements of the APVMA. However, in recent decades there has been insufficient registration of new veterinary medicines, and this low level of new registration seems increasingly to be the case in the future, not only for major species but notably for the thousands of minor species.

A survey was undertaken in 2010 to identify the veterinary medicines (Prescription Animal Remedies or Schedule 4 medicines) recommended during the undergraduate training of veterinarians in Australia and New Zealand, as well as identifying the veterinary medicines recommended in the major set of authoritative veterinary pharmacology textbooks and formularies (Mills et al 2010). A total of 978 recommended active constituents was identified. At the time there were 223 active constituents in veterinary medicines approved by the APVMA. Only 23% of the recommended actives were available in registered products. This has not changed significantly in the 13 years since this survey was undertaken.

In the decade (2010-2020) a total of 20 pharmaceutical active constituents were lost from the APVMA registration database[1], while a total of 19 approved pharmaceutical active constituents were gained in the same period (2010-2020)[2]- a net loss of one active in a decade – a decade that was

[1] Actives lost: amphotericin B; aspirin; cinchocaine; corticotropin (ACTH); difloxacin; etamiphylline; etiproston; etodolac; gramicidin; histamine; ketanserin; meclofenamic acid; medroxyprogesterone acetate; nonoxynol-9; penicillin G (benzylpenicillin); phenytoin; porcine somatotropin (PST); quinalbarbitone; ramifenazone; and tripelennamine

[2] Actives (and their products) gained: robenacoxib [ONSIOR TABLETS / INJECTION FOR DOGS / CATS] (2010); thiamazole [FELIMAZOLE COATED TABLET (treatment of feline hyperthyroidism)] (2012); dexmedetomidine [DEXDOMITOR INJECTABLE SEDATIVE AND ANALGESIC FOR DOGS / CATS] (2012); carbimazole [VIDALTA TABLETS FOR CATS (treatment of feline hyperthyroidism)] (2013); dirlotapide [SLENTROL (obesity in dogs)] (2013); imepitoin

characterised by expanding veterinary practice and increasingly sophisticated animal health and welfare needs. In the last four years (2020-2022) Schedule 4 products containing 8 new active constituents (GRAPIPRANT; PARACETAMOL; TIGILANOL TIGLATE; BEDINVETMAB; CICLESONIDE; FRUNEVETMAB; FLURALANER and POSACONAZOLE) have been registered. The rate of gain of new registered veterinary medicines is a small fraction of the ever-expanding unmet need.

Importantly, it is not only the active constituents that are needed by veterinary practitioners. The actives need to be formulated into a dosage form that is suitable for the animal to be treated. For example, formulations are needed that can be given by a suitably safe route of administration to a fear-aggressive chihuahua or a feral cat where there are few potential safe routes of administration. In view of the vast number of animal species, spanning mammals (placental (monogastric and ruminant), marsupial, monotremes), birds, reptiles, amphibians, fish, and invertebrates such as insects and arachnids, there are a massive number of formulation types needed. In addition to species variation in physiology and pharmacology, variation of size within and between species is immense. For a small animal practitioner, the smallest patients may have a bodyweight in the grams (mouse, say 20-80g), and the largest great Dane could be up to 100kg. Even within dogs, the smallest puppy could weigh approximately 300g. For zoo vets, the upper range of bodyweights treated is measured in tonnes. There is an increased client demand concerning preferences for administration of veterinary medicines If the companion animal does not like taking medications this can negatively impact the human animal bond, causing stress and risk of injury for the owner (Taylor et al 2022).

Unmet therapeutic needs

While the therapeutic needs of conventional companion animals is ever-expanding, there is also a vast number of exotic animal species with individual needs, that be appreciated by a glance at the exotic animal formulary edited by Carpenter and Harms (2023). The formulary includes sections on invertebrates (including abalone, bees, cephalopods, clams, conches, coral, cuttlefish, lobsters, oysters, polychaetes, sea urchins, shrimp, spiders, starfish), fish, amphibians, reptiles, birds (thousands of species), sugar gliders, rodents, rabbits, ferrets, miniature pigs, primates, waterfowl and wildlife (thousands of species – including more than 800 distinct Australian species). The formulary provides information on 678 pharmaceutical active constituents plus 80 combinations of these actives. Most of the medicines are included in the categories of analgesics, anaesthetics (inhalant and injectable), antiepileptics, antifungals, antibacterials, parasiticides, antiprotozoals, antivirals, chemical restraint agents, chemotherapy, and euthanasia agents. Very few (less than 5%) of the products described in this publication (now in its 6th edition) have suitable registered products available in Australia.

While Carpenter and Harms (2023) provide a global picture, closer to home and in Australia, a search of the APVMA product database (PubCris) reveals few veterinary medicines registered specifically for Australian wildlife. For example, for emus one S4 – ronidazole and one S8 – ketamine is registered, 2 active constituents for each of kangaroos, koalas and wombats (Ixodes antiserum and ketamine). Products registered with broad claim for ANIMALS, which would include Australian fauna species,

[PEXION TABLETS FOR DOGS (antiepileptic)] (2015); oclacitinib [APOQUEL TABLETS FOR DOGS (antipruritic)] (2015); pradofloxacin [VERAFLOX TABLETS FOR DOGS / CATS ANTIMICROBIAL] (2015); telmisartan [SEMINTRA ORAL SOLUTION FOR CATS (reduce proteinuria in cats with chronic kidney disease)] (2015); clodronic acid [OSPHOS SOLUTION FOR INJECTION FOR HORSES (reduce lameness)] (2016); peforelin [MAPRELIN (synchronisation of oestrus in sows)] (2016); terbinafine [OSURNIA EAR GEL FOR DOGS (antifungal)] (2016); triptorelin [OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS (synchronisation of oestrus in sows)] (2016); amlodipine [Amodip Flavoured Tablets for Cats (treatment of hypertension)] (2018); lokivetmab [CYTOPOINT Solution for Injection for Dogs (atopic dermatitis)] (2018); cimicoxib [CIMALGEX CHEWABLE TABLETS FOR DOGS (NSAID)] (2019); plasmid DNA (rE. coli DH5α pINGhT) [ONCEPT® CANINE MELANOMA VACCINE] (2019); and budesonide [DERMCARE BARAZONE BUDESONIDE LEAVE-ON CONDITIONER] (2020)

total 32 products, principally classified as euthanasia injections, tetracycline topical powder and aerosol, enrofloxacin oral and injectable products, antiseptics, disinfectants, wound treatments, probiotics, and parenteral fluids. Clearly the therapeutic formulary of registered veterinary medicines to meet the many and expanding clinical needs of Australian fauna is extremely deficient – and unlikely to change.

Registration to meet unmet needs

The regulatory process is expensive. Pharmaceutical companies are not philanthropic. Only those unmet needs likely to generate a return on investment will gain the interest of the global and domestic pharmaceutical companies. While very common problems are often well catered for with veterinary medicines, many of the species requiring treatment are considered by regulators as minor (though not considered minor by their owners) and many of the indications for treatment are minor (from the perspective of the number of animals at risk). The multitude of minor use, minor species – MUMS – clinical needs is unlikely ever to be addressed by the current registration system.

Alternative sources of veterinary medicines

An important and widely used source of veterinary medicines is derived from extra-label use (ELU) (also known as off label use) of registered veterinary medicines. ELU is defined as any use of a product that is not described in the label of the product and most commonly applies to use in the labelled species for a new indication or at a new dosage regimen (route of administration, dose rate, frequency, duration) or use in an animal species not included on the label. ELU is frequently the subject of teaching in veterinary schools, for example the use of combinations of drugs for sedation and premedication prior to anaesthesia. Furthermore, ELU is often required, for example, when there is a need to use a medicine in unusual pets, wildlife, and uncommon farm animal species such as alpacas and a potentially suitable medicine is registered for cattle and sheep. Where regulatory overview is beneficial then minor use permits can be sought from the APVMA, but in practice minor use permits are expensive, time consuming and complex to obtain, where the benefit is often much less than the effort.

A significant issue associated with ELU in food producing animals relates to the maximum residue limit (MRL) (whether available or not available) and the need to determine a WHP that allows residues associated with the ELU to deplete to concentrations less than the MRL. The risk associated with ELU leading to the MRL being exceeded is sufficiently high to substantially reduce the frequency of extra label use in food producing species.

ELU in the multitude of species not used for food production does not require consideration of a WHP. However, capturing information on the effectiveness and safety of this ELU will also have significant benefits in refining the treatment of new species. For example, sarcoptic mange in free-ranging bare-nosed wombats (*Vombatus ursinus*) is a significant source of morbidity and mortality. Collection of real-world data of the response to treatment of wombats with various forms of moxidectin revealed evidence of safe and effective use, establishing the foundation of a hypothesis to be tested in future controlled studies (Old et al 2021). The use of fluralaner has also been investigated and initial evidence supports the safe and effective use in bare-nosed wombats (Wilkinson et al 2021). If effectiveness and safety is substantiated, either or both of these treatment approaches could save the lives of many individual wombats, and potentially the viability of wombat populations, though neither approach is likely to be the subject of a label claim on a registered product, and current products are not ideal (Takano et al 2023) and could be substantially improved by pharmaceutical refinement of transdermal delivery (Bains et al 2022).

Compounded Veterinary Medicines

Over the last decade, compounded veterinary medicines (CVMs) have begun to fill the large gap between registered veterinary medicines and unmet needs. In recognition of the important role of

CVMs and the absence of regulatory clarity the AVA has prepared and distributed guidelines for the preparation and use of compounded pharmaceuticals (AVA 2020). However, there is also a need to define Good Compounding Practice for Veterinary Medicines (GCPvm) and to ensure that it is implemented. This is a task that the AVA are currently working on via the AVA Veterinary Compounding Working Group.

How important are CVMs to veterinary practice?

A survey of AVA members was undertaken in June 2020 to inquire about the use of CVMs in contemporary veterinary practice. A total of 747 responses were received in the 4 week response time permitted. Respondents were from suburban (39%), urban (22%) and rural (31%) practices, with the majority of the case load being companion animals in 71%, mixed practice in 14%, equine practice 9%, with zoo, exotic and unusual pets being the major focus in 2%.

In this study, 82% of responding veterinarians reported using CVMs, but frequency of use was low (71% of responding veterinarians used CVMs once or less each day).

With respect to adverse drug reactions, 81% of respondents reported no ADRs associated with CVMs, while 19% had experienced at least one ADR, including 1% who described frequent ADRs, 1% who experienced ADRs at the same frequency as with registered veterinary medicines and the remainder (17%) who reported ADRs occasionally to extremely rarely.

While use of CVMs is much lower than the use of registered products, CVMs nevertheless occupy an important role, which is expected to expand in the decades ahead. For example, many Australian veterinarians become "Fear Free" certified veterinarians. The Fear Free approach is designed to manage fear, anxiety and distress in animals to protect the welfare of animals and the safety of those working with them. The use of medications such as trazodone are recommended in this training program (https://fearfreepets.com/fear-free-certification-overview/).

The absence of specific training of pharmacists in the preparation of CVMs and the absence of any accreditation of pharmacists in the quality of CVMs are fundamental deficiencies that the AVA is endeavouring to address and which could be supported by a change to Section 11 of the proposed MPTG regulations to recognise the value of pharmacies that complied with a code of good manufacturing practice, such as that required by the APVMA for licensed manufacturers.

Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia

On 5 September 2019, the Australian Government Minister for Agriculture announced a comprehensive first principles review of the regulatory framework for agricultural and veterinary (agvet) chemicals. The review was to examine the agvet chemicals regulatory framework's aims, structure, and operation, and make recommendations to ensure it is contemporary, is fit for purpose and reduces unnecessary red tape.

The final report of this review was published in 2021 and included a number of statements and recommendations that recognised the increasing importance of compounded veterinary medicines. In the executive summary, the report stated that "[t]he Panel recommends better regulation of compounded veterinary products which are playing an increasingly important role in the treatment of companion animals and exotic species."

The final report further noted that "activities such as compounding veterinary medicines are not subject to the same safety and quality standards and controls as veterinary medicines in the current regulatory system. Products compounded by a veterinarian, or by a pharmacist as prescribed by a veterinarian, do not fall within the existing legal definition of a veterinary chemical product, and therefore are not captured by the APVMA's manufacturing licensing requirements."

To address the regulatory gaps and recognising the increased need of CVM's, the following two recommendations were made:

Recommendation 31

The Panel recommends that compounded veterinary products fall within the scope of the future regulatory system but are exempt from registration where they comply with the prescription protocol. In developing the protocol, the Panel recommends:

- **registered products be considered first, and compounded products are only prescribed where no suitable or available regulatory assessed products exist**
- **the prescription protocol is finalised and implemented under the single national law for control-of-use**
- **the APVMA works with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies to ensure one or more suitable manufacturing standards are established to enable said exemption.**

Recommendation 32

The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.

The AVA has supported these recommendations and has discussed them with the Pharmacy Board of Australia who recommended that AVA work with PSA to develop appropriate practice standards for CVMs.

AVA was in the process of contacting PSA when it became aware of the current consultation on the revised draft PSA Professional Practice Standards.

CONCLUSION

The practice of veterinary medicine is becoming more specialised and sophisticated as new technologies become available to help detect and diagnose disease and as new treatments are needed to manage the health and welfare of veterinary patients.

Access to high quality medicines and continual monitoring of effectiveness and safety will remain core elements of veterinary practice in the future.

The veterinary profession is constantly adopting new approaches to refine and perfect its approach to precision medicine and individualised dosing programmes. Working closely within a regulatory environment that facilitates and supports the evolution of the profession and its practices will ensure that owners and their animals receive the best possible treatment.

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