PSA Draft Professional Practice Standards

Submission of the
Australian Veterinary Association Ltd

23 March 2023

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The Australian Veterinary Association (AVA)

The Australian Veterinary Association (AVA) is the national organisation 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.

PSA 2023 Draft Professional Practice Standards – AVA Comment

Introduction

The Australian Veterinary Association (AVA) welcomes the opportunity to provide a veterinary context to the open consultation of the revised draft PSA Professional Practice Standards.

Over the last decade there has been a growing demand for compounded veterinary medicines (CVMs) in all non-production animal areas of veterinary practices, areas that include the medicine of dogs, cats, horses, other companion animal species (notably birds, fish, small mammals and reptiles), wildlife species (especially in response to natural disasters such as floods and fires), and zoo animals (for example, to treat tuberculosis in affected zoo animals). The subject of CVMs and the unmet need in veterinary practice is more comprehensively summarised in the accompanying document entitled '*Compounded Veterinary Medicines - The Growing Need. Background for the Pharmaceutical Society of Australia*' (**Appendix A**).

While the compounding of medicines for human use is undertaken in reference to the Commonwealth Therapeutic Goods Act, this Act applies exclusively to humans and does not apply to other animal species. The compounding of medicines for veterinary use is recognised in the Agricultural and Veterinary Chemicals Code Act 1994 (AgVet Code). At clause 5 on the definition of a veterinary chemical product, compounded veterinary medicines are specifically excluded from the AgVet Code as follows:

5 Definition of *veterinary chemical product*

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(4) 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; or

(b) a substance or mixture of substances declared by the regulations not to be a veterinary chemical product.

The professional interaction of the veterinary prescriber providing instructions to the pharmacist and the pharmacist preparing the compounded veterinary medicine is quite distinct from the interaction between a human healthcare provider and a pharmacist. The interaction is different as the relevant legislation is different and, importantly, while pharmacists receive significant undergraduate and postgraduate continuing professional development on matters of human health and wellbeing, no comparable education, training and experience is gained on the myriad animal species other than humans. It is the veterinarian that is trained and skilled in the detection and diagnosis of disorders and diseases of animals and is experienced in the development of treatment plans and medicine administration and monitoring. It is the veterinarian who will be the sole source of instructions to a pharmacist to compound a veterinary medicine.

In most situations the CVM will be returned to the prescribing veterinarian in order that the veterinarian can explain to the owner of the animal to be treated about the CVM and how it is to be safely and effectively administered, how to monitor the response to treatment, what clinical response is expected and when further consultation is necessary. Many of the activities associated with pharmacists and their human clients are replaced by the veterinarian and owner and animal in the context of CVMs.

It is in light of this different interaction of veterinarian and pharmacist that comments are provided on the revised draft standard.

REVIEW OF REVISED DRAFT PROFESSIONAL PRACTICE STANDARDS

SECTION	COMMENTS
ABOUT THE STANDARDS	
Purpose	Relevance to pharmacists compounding veterinary medicines (CVMs) needs to be enhanced (see below)
Relationship to other guidance documents	The AVA have developed "Guidelines for the preparation and use of compounded pharmaceuticals 2020"
Descriptors of other guidance and regulation of pharmacy practice	
HOW TO USE THE STANDARDS IN PRACTICE	The vaccination example highlights differences between pharmacist-human patient interaction and pharmacist-veterinarian interaction – it would not be appropriate for pharmacists to vaccinate animals, for example, horses, sheep and cattle.
TERMINOLOGY	The definition of compounding differs according to whether the compounding is for human use or for veterinary use. The dispensing of a CVM is unlikely to require 'advice to the patient'. Hazardous substances can pose a health or physical hazard to animal patients as well as to humans. Healthcare professional does not include a veterinarian and raises the question as to where veterinarians might be placed. The entry for 'patient' is the sole place where mention of an animal patient is included in the draft PPS. Pharmacists could dispense non-prescription veterinary medicines to an animal owner but are not trained to give advice on appropriate treatment or administration. The term 'therapeutic good' should apply only to humans. It is noted that the references do not include any veterinary sources.

CORE STANDARDS	
Patient-centred care	In most cases the patient-centred care will be for a human patient. The equivalent care for an animal patient is provided by the prescribing veterinarian – underpinning the unique role and relationship between pharmacist and veterinarian.
Responsibility and accountability	There is a responsibility for continuing professional development, a subject that the AVA is keen to discuss with PSA with respect to CVMs. Currently there is no independent CPD available, though AVA are aware of at least one university pharmacy school that is prepared to develop suitable resources.
Interprofessional collaboration	The interprofessional collaboration of pharmacist and healthcare team is well described. In addition, there is a separate and distinct interprofessinal collaboration between pharmacist and veterinarian, each having individual responsibilities in the prescribing and dispensing of CVMs as well as having shared responsibilities.
Service delivery	Access to evidence-based resources for CVMs relevant to Australian prescribing is a topic of discussion between AVA and PSA.
PRESCRIBING	
Prescribing	This section refers to therapeutic goods and is therefore not directly applicable to veterinary medicines.
Minor ailment management	For animal patients, diagnosis of minor ailments will be an act of veterinary science rather than an act of pharmacy practice.
Dispensing and preparation	
Dispensing	This section refers to therapeutic goods and is not directly applicable to the dispensing of veterinary medicines, which in most cases WILL be dispensed to the veterinary prescriber who can then discuss and demonstrate appropriate use to the animal owner.
Compounding	The objectives of safe, effective and appropriate quality equally apply to CVMs, however, it is unusual for the animal owner to provide the prescription, it is most likely presented to the pharmacist by the prescribing veterinarian. In this case patient identification, patient needs assessment and advice will be the responsibility of the prescribing veterinarian.
Medicine packing	Identification of the person receiving the medicine will equate to identification of the prescribing veterinarian in most cases and advice on safe and effective use and monitoring will form further responsibilities of the prescribing veterinarian.

Safe and secure handling of therapeutic goods	Veterinary medicines could be handled in the same way as set out for therapeutic goods.
ADMINISTRATION	
Administration, including supervised administration, of a medicine	Pharmacists are not trained to administer veterinary medicines to the thousands of species of animals that may be the subject of treatment (for example, snakes, primates, yellow tailed black cockatoo, southern bluefin tuna). Administration is a reasonable responsibility of the prescribing veterinarian who will be able to ensure the procedure is safe to owner and to animal patient. When assessing administration, it is appropriately out of scope of the pharmacist who can refer the activity to the prescribing veterinarian.
MONITORING	
Medication review	For an animal patient, most aspects of the medication review are responsibilities of the veterinarian.
Medicine use evaluation	For an animal patient, most aspects of the medication use evaluation are responsibilities of the veterinarian.
POPULATION HEALTH	This section appears to be directed at human patients only.
Medicines and health information	Responsibility of the prescribing veterinarian.
Screening and risk assessment	Responsibility of the prescribing veterinarian.
Health promotion and education	Responsibility of the prescribing veterinarian.
Chronic disease management	Responsibility of the prescribing veterinarian.
REFERENCES	It is noted that the reference list contains no veterinary examples of compounded medicines.

Additional comments

It is a result of the growing reliance on compounded veterinary medicines that there is increased interest by the AVA to ensure that the PSA Professional Practice Standards provide appropriate and accurate guidance to pharmacists.

Definition of Compounding of Veterinary Medicines

The definition appropriate to CVMs does not derive from the TG Act and is not constrained by the requirement for a single unit of issue, an identified patient and an identified need. The veterinarian is responsible for maintaining records of the patient and the justification for the prescription.

Dispensing of Compounded Veterinary Medicines

It is appropriate to dispense CVMs to the prescribing veterinarian who is responsible for ensuring the CVM is safe and effective and can be readily administered to the animal patient. The pharmacist is responsible for the quality of the CVM, but the veterinarian should assume responsibility for safety and effectiveness.

Continuing Education of Pharmacists on CVMs

The AVA is not aware of any independent Australian undergraduate or continuing professional development resources currently available addressing the subject of CVMs. AVA is aware of at least one university pharmacy school that is interested in preparing resources that could be made available online.

The AVA is interested in working with PSA to develop a curriculum for CPD.

Collaboration between AVA and PSA

AVA is keen to advance the recommendations set out in the final report of the Independent Review of the Pesticides and Veterinary Regulatory System in Australia (AgVet Review). The quality of CVMs remains an important but poorly regulated area. It is only when CVMs are of a reliable and reproducible quality that animal health and welfare can benefit. We are sure that AVA and PSA working together can provide a high quality future of CVMs.

Attachments

Appendix A: Compounded Veterinary Medicines - The Growing Need. Background for the Pharmaceutical Society of Australia.

AVA Contact:

Dr Melanie Latter
E: melanie.latter@ava.com.au

Appendix A

COMPOUNDED VETERINARY MEDICINES - THE GROWING NEED

Background for Pharmaceutical Society of Australia

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. This increasingly requires access to a vast number of veterinary medicines of suitable quality, safety, and effectiveness and with a suitable dosage form, 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. 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 animal species, veterinarians fulfill an essential role in caring for 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 degree of 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 biology, chemistry, 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.

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, exotic animals, 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), 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 and animal 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.

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 last decade (2010-2020) a total of 20 pharmaceutical active constituents were lost from the APVMA approved list[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 that was characterised by expanding veterinary practice and increasingly sophisticated animal health and welfare needs.

[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 [PEXION TABLETS FOR DOGS (antiepileptic)] (2015); oclacitinib [APOQUEL TABLETS FOR DOGS (antipruritic)] (2015); pradofloxacin [VERAFLOX TABLETS FOR DOGS / CATS ANTIMICROBIAL] (2015); telmisartan [SEMINTRA ORAL

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 an angry chihuahua or a feral cat where there are few potential reliable 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, 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 around 94kg. Even within dogs, the smallest would weigh approximately 800g. For zoo vets, the upper range of bodyweights treated is measured in tonnes. There is an increased client demand about preference for animal treatment, 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.

Unmet therapeutic needs

The therapeutic needs of the vast number of exotic animal species can be appreciated by a glance at the exotic animal formulary edited by Carpenter and Marion (2018). 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, hedgehogs, 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, antiparasitics, antiprotozoals, antivirals, chemical restraint agents, chemotherapy, and euthanasia agents. Very few (less than 5%) of the products described in this publication (now in its 5th edition) have suitable registered products available in Australia.

While Carpenter and Marion (2018) provide a global picture, closer to home and in Australia, a search of the APVMA product database (PubCris) reveals no veterinary medicines registered specifically for emus, 3 products for each of kangaroos and wombats (one active constituent in 3 different ketamine injectable products) and 4 products for the koala (2 active constituents, being 3 ketamine injectables and paralysis tick antiserum). Products registered with broad claim for ANIMALS, which would include Australian fauna species, 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

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)

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 often required, for example, when there is a need to use a medicine in uncommon 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 wombats, though neither approach is likely to be the subject of a label claim on a registered product.

Compounded Veterinary Medicines

Over the last decade, compounded veterinary medicines (CVMs) have begun to fill the large gap between registered veterinary medicine and unmet need. 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 39% suburban, 22% urban and 31% rural 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. 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.

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

On 5 September 2019, the Federal 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. 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.

REFERENCES

Animal Medicines Australia and Newgate Research (2022). Pets in Australia: A national survey of pets and people. Canberra, Animal Medicines Australia Pty Ltd.

AVA (Australian Veterinary Association) (2020). Guidelines for the preparation and use of compounded pharmaceuticals. Sydney, Australian Veterinary Association.

Beaton, G. R. (2010). "Why professionalism is still relevant." University of Melbourne Legal Studies Research Paper(445): 1-23.

Carpenter, J. W. and C. J. Marion (2018). Exotic Animal Formulary (Fifth Edition). St. Louis, Missouri, Elsevier.

Mills, P., S. W. Page and A. Craig (2011). Veterinary pharmacology curriculum renewal to improve graduate outcomes and public safety. Sydney, NSW, Australian Learning and Teaching Council (ALTC).

Old, J. M., C. J. A. Skelton and H. J. Stannard (2021). "The use of Cydectin® by wildlife carers to treat sarcoptic mange in free-ranging bare-nosed wombats (Vombatus ursinus)." Parasitology Research **120**(3): 1077-1090.

Susskind, R. E. and D. Susskind (2015). The future of the professions: How technology will transform the work of human experts. New York, New York, Oxford University Press.

Vandeweerd, J. M., S. Vandeweerd, C. Gustin, G. Keesemaecker, C. Cambier, P. Clegg, C. Saegerman, A. Reda, P. Perrenoud and P. Gustin (2012). "Understanding veterinary practitioners' decision-making process: implications for veterinary medical education." J Vet Med Educ **39**(2): 142-151.

Wilkinson, V., K. Takano, D. Nichols, A. Martin, R. Holme, D. Phalen, K. Mounsey, M. Charleston, A. Kreiss, R. Pye, E. Browne, C. Næsborg-Nielsen, S. A. Richards and S. Carver (2021). "Fluralaner as a novel treatment for sarcoptic mange in the bare-nosed wombat (Vombatus ursinus): safety, pharmacokinetics, efficacy and practicable use." Parasit Vectors **14**(1): 18.