Guidelines on compounding of medicines review - response template

The Pharmacy Board of Australia is inviting feedback on its draft revised *Guidelines for compounding of medicines* (the draft revised guidelines). Optional questions have been provided below and you may wish to address some or all of these in your response.

Published submissions will include the names (if provided) of the individuals and/or organisations making the submission unless confidentiality is requested.

Do you want your responses to be published after public consultation?

☒ Yes, I want my responses to be published after public consultation

☐ No, I do not want my responses to be published after public consultation

Submissions for website publication should be sent in Word format or equivalent.[1]

Name: _____ _____

Organisation: ACT Veterinary Practitioners Board _____

Contact email: _____

Please note this response template contains the same questions as the online survey. Please choose only ONE method of responding to avoid duplicating your submission.

[1] We aim to publish documents in accessible formats (such as word files) to meet international website accessibility guidelines. Therefore, while you are welcome to supply a PDF file of your feedback, we ask that you also provide a text or word file. More information about this is available at https://www.ahpra.gov.au/About-Ahpra/Accessibility.aspx

	Question	Your feedback (include guideline number/section)
	Introduction – explanatory note	Not all medicines required by veterinarians to treat their patients are available as registered veterinary medicines. This is because of the expanding breadth of practice in the veterinary field: from major and minor production species, to companion animals, birds, wildlife, exotic pets, and zoo animals. Each species has its own unique needs for veterinary medicines. Variation of size between species is immense. For a small animal practitioner, the smallest patients may have a bodyweight in the grams (mouse or bird, say 30-80g). For zoo vets, the upper range of bodyweights treated is measured in tonnes. Variation *within* species can also be significant (eg dogs may vary from 800g to the largest great Dane at around 95kg). Thus often the actives need to be formulated into a dosage form that is suitable for the animal to be treated. Further, depending on the species, flavouring, palatability or method of administration may also be an issue. In addition to this, the scope and specialisation of veterinary practice has also expanded as more sophisticated and complex treatments are expected from the animal-owning public. While very common problems are often well catered for with registered veterinary medicines, the multitude of minor use, minor species clinical needs is unlikely ever to be addressed by the current registration system, as pharmaceutical companies cannot justify the expense to develop and register drugs suitable for these relatively niche needs. This is why over the last decade, compounded veterinary medicines have begun to fill the large gap between registered veterinary medicine and this unmet need. It will remain important that veterinary practitioners are able to use their clinical judgement to prescribe a compounded medicine where no *suitable* registered veterinary product is available. The ACT Veterinary Practitioners Board therefore appreciates the Pharmacy Board's attention to veterinary needs as part of their review of their *Guidelines for compounding of medicines*, and the efforts made to clarify the differences in context from the human compounding situation. We would be grateful if the following comments could be taken into consideration:

	Question	Your feedback (include guideline number/section)
1	The revised compounding guidelines include additional content on medicine supply pathways to consider before deciding if it is appropriate to compound a medicine (Guideline 1 When to compound medicines). **Is the new content on medicine supply pathways clear and helpful? Why or why not?**	**Guidance 1.1.1: "Note for animal patients":** The ACT Veterinary Practitioners Board recommends that an additional clause (shown below in upper case) is added to the text: *"Registered veterinary chemical products for use in Australia are assessed for quality, efficacy and safety. If a suitable registered veterinary chemical product (or combination of registered veterinary chemical products) is available, a pharmacist must not:* *a. offer to compound the medicine, including if the medicine can be compounded at a lower price than the available veterinary chemical product, or* *b. compound a slightly different medicine that is unlikely to produce a different therapeutic outcome to an available veterinary chemical product – UNLESS FOR REASONS OF DOSAGE, FORMULATION, FLAVOURING OR METHOD OF ADMINISTRATION, THE COMPOUNDED PRODUCT WILL PROVIDE A CLINICAL ADVANTAGE."* The reason for including the additional text is that the term "slightly different" may be hard to interpret – however the clarification shown in upper case lettering would describe the scenarios and justifications for compounding something "different" to an available registered veterinary product.
2	The compounding guidelines advise that a copy of the formula for their compounded medicine (listing all active ingredients and their strengths, and all inactive ingredients) must be provided to the patient when requested (Guideline 13 Supporting informed patient choice). Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. **Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?**	

	Question	Your feedback (include guideline number/section)
3	The revised compounding guidelines include content that is specific to medicines compounded for animal patients. **Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?**	The new content for animal compounding goes some way to helping to clarify the different context within which veterinary compounded medicines are required. However please note the additional important text that we are suggesting should be included in Guidelines 1.1.1, Guideline 5.2, and Guideline 7, to provide further clarity.
4	**Is there any content that needs to be changed, added or deleted in the revised guidelines? If so, please provide your suggestions and reasons.**	**Yes, please see note above about additions requested for Guideline 1.1.1** Please also note the following request for aditional veterinary-specific content in Guidelines 5.2 and 7: **Guideline 5.2 "Quantity to be supplied"** For the reasons outlined in the introductory section, the use of compounded products is often routine (rather than the exception) in some types of veterinary practice (eg emergency practice, avian practice, unusual pets practice - reptiles and exotics etc). For this reason, veterinarians in such practices need to be able to have compounded products on the shelf which have been prepared for them in advance, in anticipation of use. It is important therefore, that veterinarians are not constrained by the requirement for a single unit of issue, and an identified patient, when ordering compounded medicines. We recognise that Guideline 5.2 allows for this and has given an example of a herd situation, but feel some additional clarification would be helpful, as shown in upper case below: *"Note for animal patients: In the case of compounded veterinary medicines, a pharmacist may supply more than a single unit of issue of a medicine when supplied in response to instructions from a veterinarian (e.g. supply for multiple animals such as a herd), OR SUPPLY IN ANTICIPATION OF USE FOR EXPECTED TREATMENTS WHERE NO SUITABLE REGISTERED VETERINARY MEDICINE IS AVAILABLE. COMPOUNDED VETERINARY MEDICINES WHICH HAVE BEEN SUPPLIED TO BE AVAILABLE IN ANTICIPATION OF USE DO NOT NEED TO BE LABELLED WITH THE NAME OF THE PARTICULAR ANIMAL PATIENT OR THEIR OWNER, AS THE IDENTITY OF THE PARTICULAR ANIMAL PATIENT WILL NOT BE KNOWN AT THE TIME OF SUPPLY TO THE VETERINARIAN. "*

	Question	Your feedback (include guideline number/section)
		Guideline 7. Batch Preparation Consistent with the above, we also suggest an additional paragraph is added to section 7 along the lines of: *A PHARMACIST MAY COMPOUND A BATCH OF MULTIPLE UNITS OF ISSUE AFTER RECEIVING INSTRUCTIONS FROM A VETERINARIAN TO COMPOUND A MEDICINE FOR MORE THAN ONE EXISTING OR FUTURE ANIMAL PATIENT, OR GROUP OF ANIMALS. VETERINARIANS ARE NOT REQUIRED TO PROVIDE SEPARATE INSTRUCTIONS FOR INDIVIDUAL NAMED ANIMALS WHEN INSTRUCTING A PHARMACIST TO COMPOUND A MEDICINE IN ANTICIPATION OF USE OR FOR GROUPS OF ANIMALS*.
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	
6	**Please provide any other feedback about the revised guidelines.**	**Training of pharmacists in veterinary compounding** At this stage we are unaware of any specific training of pharmacists in the preparation of compounded veterinary medicines. Perhaps consideration could be given to developing targeted post-graduate CPD for pharmacists in veterinary compounding.
7	The Board proposes to retire the *Professional practice profile* for pharmacists undertaking complex compounding, as a professional practice profile should be practitioner specific, describe an individual's scope of practice and is not common to all pharmacists undertaking complex compounding. Individuals should develop their own practice profile by selecting the relevant competencies from the competency standards and customising them for use in their own practice setting. **Do you agree with the Board's proposal to retire the currently published *Professional practice profile* for**	

	Question	Your feedback (include guideline number/section)
	pharmacists undertaking complex compounding? Why or why not?	
8	The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation. **Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?**	