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]

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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)
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?**	**Yes, however please see comments and suggested minor amendments to Guideline 1 shown in table provided below (AVA addendum setting out specific comments against specific numbered guidelines).**
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?**	**COMMENT: AVA supports informed patient choice, but also recognises that pharmacists should have a right to develop novel, safe and effective formulations and that disclosing the composition is inadequate to ensure that the compounded veterinary medicine can be replicated by a third party.**
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 AVA appreciates the inclusion of content relevant to compounded veterinary medicines. We have made some comments and suggested amendments to further enhance clarity – please see the table provided below (AVA addendum setting out specific comments against specific numbered guidelines).**
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.**	**AVA has made some comments and suggested amendments to further enhance clarity around veterinary compounding – please see the table provided below (AVA addendum setting out specific comments against specific numbered guidelines).**
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.**	**Please see table addendum.**

	Question	Your feedback (include guideline number/section)
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 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?**	

AVA addendum setting out specific comments against specific numbered guidelines:

COMPOUNDING GUIDELINE	AVA COMMENTS
Introduction	
Page 2/32 "These guidelines are intended to support good practice by pharmacists when compounding medicines for human and animal patients. Pharmacists who compound medicines or oversee the compounding of medicines must ensure that at, all times, compounding practices are:	

• compliant with relevant legislation”	
Quality Standards	
Guidelines	
1 When to compound medicines	
Medicines for human use	
Veterinary medicines	
1.1 Considerations before compounding a medicine	
Medicines should only be compounded in circumstances when:	
a. an appropriate commercial medicine does not exist, is unavailable or cannot be accessed within the timeframe that the medicine is required for use by the patient, or	
b. a commercial medicine is unsuitable (for example, if a patient has a known allergy to an excipient in the medicine or the dose forms available are unsuitable)	
c. required for the purpose of research sanctioned by a recognised human OR ANIMAL research ethics committee	AMENDMENT: Add “or animal”
Note for animal patients:	
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.	COMMENT: Important to provide guidance on the meaning of SLIGHTLY DIFFERENT. For animal patients, a major benefit of compounding is to facilitate administration and improve compliance with the recommended dose regimen. For example, palatability enhancement is a vital component, as is matching dose volume and dosage form to the needs of the animal species to be treated (which may vary in bodyweight from 10g to 5,000,000g).
1.2 Obligations when a prescribed or requested medicine cannot be compounded	

2 Competence to undertake compounding	
Veterinary medicines Pharmacists who intend to compound simple and complex veterinary medicines are expected to have completed CPD (education and training) in the compounding of medicines for the treatment of animals. For more information on veterinary compounding, refer to the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook.*	COMMENT: AVA is not aware of any currently available independent Australian veterinary compounding CPD. This is an area which needs to be addressed and AVA is currently examining options for provision of independent education in veterinary compounding. AVA is not aware of any specific guidance on veterinary compounding provided by the current edition of the *Australian Pharmaceutical Formulary and Handbook.*
3 Quality assurance	COMMENT: AVA believes high standards of QA that are independently assessed is an essential element of appropriate veterinary compounding practice
3.1 Sterile medicines	
3.2 Self-assessment and audit	
4 Facilities, equipment, working environments, materials and support staff	
Starting materials The *Australian Pharmaceutical Formulary and Handbook*, states that: • All starting materials should be produced by manufacturers with suitably approved quality assurance and quality control procedures, including appropriate licensing and/or certification. • Australian manufacturers should hold a Licence to Manufacture Therapeutic Goods issued by the TGA to manufacture the relevant ingredients. • Overseas manufacturers should hold a certificate of GMP compliance or equivalent accreditation from a regulatory or accrediting authority equivalent to the TGA.	AMENDMENT: AVA requests following changes: • Australian manufacturers of HUMAN MEDICINES should hold a Licence to Manufacture Therapeutic Goods issued by the TGA to manufacture the relevant ingredients. • Overseas manufacturers should hold a certificate of GMP compliance or equivalent accreditation from a regulatory or accrediting authority equivalent to the TGA OR APVMA AS APPROPRIATE.
4.1 Risk assessment process for facilities and equipment	
4.2 Starting materials	
4.3 Supervision of support staff i. counsel and ensure the patient (or in the case of an animal patient, the owner) is given relevant information about the compounded medicine.	AMENDMENT: With respect to counselling: AVA considers that counselling of the owner of an animal recipient of a compounded medicine is a joint responsibility of the pharmacist and the veterinarian. As the owner is infrequently in direct contact with the compounding pharmacist, the pharmacist should supply the compounded product information for counselling either directly to the owner if present, or, as is most likely the case, indirectly to the owner via the veterinarian. In addition to ensuring the owner understands the pharmacist counsel, the

	veterinarian has the responsibility for ensuring the owner understands the expected response of the patient to treatment with the compounded medicine and can reliably administer the medicine.
5 Formulation considerations	
5.1 Formulations for which precedents do not exist If a medicine is compounded under these circumstances, the evidence supporting the decision should be documented and referenced in the risk assessment. The pharmacist must also ensure that the patient has been advised that the compounding has taken place under these circumstances. In the absence of documented evidence, pharmacists must not compound such medicines.	AMENDMENT: AVA proposes the following amendment" If a medicine is compounded under these circumstances, the evidence supporting the decision should be documented and referenced in the risk assessment. The pharmacist must also ensure that the patient, OR IN THE CASE OF A VETERINARY COMPOUNDED MEDICINE, THE ANIMAL OWNER, has been advised that the compounding has taken place under these circumstances. In the absence of documented evidence, pharmacists must not compound such medicines.
5.2 Quantity to be supplied 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).	COMMENT: In many clinical situations, for example in exotic animal practice, for oncology practice, for ophthalmologists, there are few or no suitable registered veterinary medicines available. In these frequently encountered situations it is essential to have necessary veterinary medicines available in practice at the time of future consultations. In addition to supplying compounded medicines for groups of animals (eg a herd) it is also necessary to have such medicines available for a series of unrelated individual patients.
5.3 Modification of commercial medicines	
5.4 Risk assessment process for compounded medicines	COMMENT: While the pharmacist can identify and manage the pharmaceutical risks, those risks related to the patient will need to be assessed and managed by the veterinarian. Such risks and their management should be part of the counselling provided by the veterinarian.
5.5 Consistency of supply	COMMENT: For compounded veterinary medicines there are few or no published formulae for most of the needed products (for example, analgesics for use in Australian reptile or avian species). It is therefore considered appropriate for pharmacists to develop proprietary formulations in consultation with a veterinarian. While providing a list of active and inactive constituents is reasonable to support animal health and welfare, a formula is insufficient (as experience with registered medicines has revealed) information on which to base a bioequivalent

	medicine, given the significant impact of product specifications and the detailed method of manufacture.
6 Assigning expiry dates to compounded medicines	
Expiry dates of compounded sterile injectable medicines An expiry date of longer than 24 hours may be assigned to a compounded sterile injectable medicine only if the pharmacist meets all the necessary conditions outlined in the Compounding section of the current edition of the Australian Pharmaceutical Formulary and Handbook.	AMENDMENT: The guideline refers to the USP-NP in several places (including in Guideline 6) and it seems reasonable to acknowledge and accept the recommendations on sterility shelf life set out in the USP-NP (ie 72h). In many cases in veterinary practice, for example ophthalmology practice, it is necessary to have products available for emergency and other uses. Such medicines require the longest possible shelf-life consistent with product experience and available evidence.
7 Batch preparation	COMMENT: AVA recognises that for compounded veterinary medicines, batch preparation may be more frequently required but must be undertaken in a way that ensures high standards of quality is maintained, preferable by practices consistent with GMP.
8 Managing risks that may lead to injury	
9 Documentation	
10 Packaging and labelling requirements Pharmacists are legally obligated to package and label compounded medicines in accordance with the *Poisons Standard* and relevant state and territory legislation.	COMMENT: When compounded veterinary medicines are supplied to a veterinarian for emergency use, the owner's name and the kind of animal will not be known at the time of dispensing, but will be included on the label provided to the owner presenting an animal to the veterinarian.
11 Counselling and provision of information on compounded medicines	COMMENT: Please note comments in 4.3 above.
12 Reporting of adverse events	COMMENT: All reported suspected adverse events should also be investigated by the pharmacist (for pharmaceutical quality) and the veterinarian (for clinical aspects).
13 Supporting informed patient choice	COMMENT: AVA supports informed patient choice, but also recognises that pharmacists should have a right to develop novel, safe and effective formulations and that disclosing the composition is inadequate to ensure that the compounded veterinary medicine can be replicated by a third party.
14 Advertising	
15 Reference texts and other sources of information relevant to compounding	AMENDMENT: AVA acknowledges and supports the statement: "Given the complex differences between animal species, collaboration with a veterinary PRACTITIONER may also be required to assure the pharmacist

	that the compounded medicine is safe and appropriate for a particular animal patient."
Definitions	
Board references	
Review	
ATTACHMENT B 1.1 Considerations before compounding a medicine	AMENDMENT: definition of a "commercial medicine" added, which includes medicines on the ARTG and medicines accessed through other pathways such as the Special Access Scheme, AND FOR COMPOUNDED VETERINARY MEDICINES APVMA PUBCRIS, this has changed from the previous definition which only included medicines on the ARTG"
ATTACHMENT C What can I expect from my pharmacist when I get my compounded medicine?	• AMENDMENT: IN THE CASE OF COMPOUNDED VETERINARY MEDICINES, COUNSELLING AND TREATMENT INFORMATION IS APPROPRIATELY PROVIDED TO THE OWNER OF THE PATIENT BY THE PRESCRIBING VETERINARIAN