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: _____[redacted]

Organisation: ____Alfred Health, Melbourne_____

Contact email: ____[redacted]_____

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?**	The new content on medicine supply pathways are clear and helpful. The guidelines provide a stepwise, approach to decision making (including the consideration of unregistered available formulations such as overseas medication including Section 19A, SAS, AP and Clinical Trials schemes. The guideline describes risk associated with unnecessary compounding of medicines. The guideline would benefit from advice surrounding use of approved or recognised formulas as a preference to personal recommendations, requests or formulas. Section 1.1.6 states patient consent is required prior to agreeing to supply a compounded medicine. This must be informed consent, and guidance for documentation of the consent (including information provided and circumstances in which consent may no longer be considered valid and/or a new consent must be obtained and recorded) would be useful both in the community and hospital setting which present different challenges. In the hospital setting, the patient may not be seen by the compounding pharmacy, and the responsibility for consent is implied (meaning that when the patient passively cooperates in process such as taking medication they provide consent) and/or multidisciplinary – particularly when responsibility for supply of medications transfer to the community pharmacy.
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?**	The formula for compounded medicine should *not* be provided in full when requested by the patient unless there is an identified reason. It is reasonable to supply full details of active ingredients only unless there are specific reasons fordoing so eg known allergies to other inactive ingredients, Patient choice can continue to be supported with an abbreviated formula, which lists active (and inactive) ingredients, though it is not necessary for the strengths of inactive ingredients to also be included. This approach would be in line with other medicines or food products where ingredients are included in

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		labelling or consumer/patient information, though explicit details about formulas/recipes are excluded. Additionally, if patients are provided with formulas of compounded medicines, there could be increased risk of patients attempting to personally compound formulas and/ or unregulated sharing of formulas with family and friends. Formulas may be useful to pass to other healthcare professionals eg for a patient on discharge from hospital. Clarity regarding the accountability for the formula eg using a recognised formula or source eg British Pharmacopoeia, and the implications of compounding a product against a 'recommendation' or request from an individual healthcare professional is also required.
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 content that is specific to medicines for animal patients is clear, though not relevant to this particular major metropolitan hospital. More specific guidance may be necessary for facilities that do compound both human and animal products to ensure separation of equipment, working environments and materials. Eg whilst human medications may be used to compound medications for animals, an animal formulation should be used as a preference if available. An animal product must never be used to compound medications for human use.
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.**	Risk Assessment: *"A risk assessment including a clinical justification for compounding must be completed for each request for a compounded medicine"* *"A risk assessment should be documented with each request for a compounded medicine (including repeats) and must consider any risks specific to the individual patient."* Documented risk assessments for each individual patient request may not be practical within a major metropolitan hospital setting especially as this may be already approved within a hospital formulary so would include an exclusion for this .

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		Within Pharmacy, rigorous training, credentialing and auditing of staff and facilities are completed frequently (including internal and external review) to maintain competency and risk assessment of compounding. Each compounding formula are evidenced based and referenced.
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	The language used and structure of the revised guidelines is helpful. There is a focus on governance of processes within the revised guidelines, with a move away from specific information, which may not be as translatable into various different working environments.
6	**Please provide any other feedback about the revised guidelines.**	Specific consideration should be given to: - Consideration of implied consent in a variety off settings - obtaining and documenting informed patient consent and necessary counselling for patients (see above) particularly in the hospital setting where the pharmacist may not see the patient - consideration of when consent may be no longer considered implied or valid - Options for patients to obtain compounded medications when a local compounding pharmacy is not available; pharmacies that do not wish to undertake compounding may need to purchase these medications from another pharmacy whilst still retaining responsibility for patient formation and consent. - Advised action for pharmacists when asked to compound medications that are not recommended or potentially unsafe to be used in the way intended by the formulation
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	The *Professional practice profile* for pharmacists undertaking complex compounding should be retired. It provides a sound structure to demonstrate understanding and skills as a pharmacist, though is general in nature and may not be as applicable to a competent complex compounding pharmacist.

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	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?**	The Board should publish the fact sheet on its website. Providing open access to information regarding compounded medicines encourages informed patient choice, andeducation It will also facilitate accountability from health professionals requesting and involved in compounding medications.