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: _____Medicinal Cannabis Industry Australia_____

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 revised compounding guidelines are clear and helpful.
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?**	A patient should be provided the formula for the compounded medicine. Information included with the formula should be expiry date/shelf life and for compounded medicinal cannabis products, the percentage of active cannabinoids.
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?**	No comment.
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.**	1.1 Consideration before compounding a medicine 1.1.1 The availability of a commercial medicine A medicine (whether prescribed by an authorised prescriber or not) ~~should~~ must not be compounded if: a. a commercial medicine is a suitable treatment option for the patient, or b. the compounded medicine would be a close formulation to that of an available and suitable commercial medicine, or combination of commercial medicines, and is unlikely to produce a different therapeutic outcome, or

	Question	Your feedback (include guideline number/section)
		c. a commercial medicine becomes available, is suitable and can be accessed within the timeframe that the medicine is required for use by the patient **Comment: the guidelines need to be clearer so that the compounding pharmacists know that they are required to fully investigate if there is an existing available product prior to compounding.** **4.2 Starting materials** A pharmacist must obtain and retain the necessary evidence to demonstrate that all ingredients comply with pharmacopoeial standards or other relevant standards and are safe for human use (or animal use for veterinary medicines) before using the ingredient in a compounded medicine. **Comment: The guidelines need to ensure that batch specific compliance documentation must be kept on file.**
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	As above, there is potential to further improve the clarity of the guidelines.
6	**Please provide any other feedback about the revised guidelines.**	There should be firmer guidelines as to whether the presented prescription should be compounded or not as currently some compounding pharmacists routinely compound medicinal cannabis preparations, and even substitute currently available commercial medicinal cannabis compounds, and ignore the availability of similar or almost identical products that are available in the market.
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.	Given the large and growing volumes of medical cannabis products currently available on the commercial market we believe that compounding medical cannabis preparations is unnecessary and is certainly not classified as complex compounding by definition. We agree that the board should retire the current professional practise profile for pharmacists in complex compounding

	Question	Your feedback (include guideline number/section)
	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?**	We support the publication of fact sheets on the Board's website for pharmacists and members of the public to access to provide full transparency for all stakeholders as to the guidelines around compounding