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: Jerry Yik, Head of Policy and Advocacy

Organisation: The Society of Hospital Pharmacists of Australia (SHPA)

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?**	SHPA believes that the new content on medicine supply pathways is clear and helpful. SHPA welcomes the updated content to include the new regulations as set out in the Therapeutic Goods Regulations 1990, where the pharmacist has received a prescription or order for the medicine before it is compounded, or the medicine is considered by the hospital's drug and therapeutic committee to be appropriate for compounding in anticipation of being needed to treat the patient. SHPA advocated for this important regulation change to occur and is pleased to see the PBA guidelines on compounding of medicines reflecting this, improving timely and safe patient access to critical medicines. SHPA supports the clear guidance on the considerations to make before compounding a medicine and the emphasis on only compounding medicines when an appropriate commercial medicine does not exist.
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?**	SHPA believes patients must be supported and empowered in joint decision making around their treatment. This includes transparency regarding the ingredients in their compounded medicines by request and is in line with practice seen internationally. It is also in the best interests of patient safety for the patient and carers to be aware of all active ingredients should an adverse reaction or unexpected outcome occur.
3	The revised compounding guidelines include content that is specific to medicines compounded for animal patients.	Not applicable.

	Question	Your feedback (include guideline number/section)
	Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?	
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.**	SHPA believes that the revised content is appropriate.
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	SHPA suggests that the case studies are placed in an appendix rather than in the main body of text to improve flow and readability.
6	**Please provide any other feedback about the revised guidelines.**	SHPA welcomes the reference to SHPA Standards of Practice and Guidelines outlined in the 'Practice standards and guidelines' section of the Guideline. However, please note the following SHPA references are current, however are undergoing review: ▪ The Society of Hospital Pharmacists of Australia (SHPA) SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments ▪ The Society of Hospital Pharmacists of Australia SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments ▪ The Society of Hospital Pharmacists of Australia SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments
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.	SHPA agrees that the 'Professional practice profile for pharmacists undertaking complex compounding' is not necessary and does not exist for other specialties. Consensus amongst members indicates that the professional practice profile is rarely used in hospital practice. Instead, members refer to the SHPA Standards of Practice and Guidelines indicated in the consultation document, under 'Practice standards and guidelines'. In addition, due to the complexities and variations in compounding services across Australia, health services employ their own training requirements and

	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?	standard operating procedures. It is expected that as with other specialities, pharmacists will also customise the relevant competencies required for their specific area of practice.
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?**	SHPA believes that the fact sheet should be published on its website. This facilitates full transparency as patients may not fully understand the nature of compounding and its associated risks. It is important to inform patients that the medication they are receiving is a compounded item and does not therefore meet the same requirements that a registered product would have.