

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: The Pharmacy Guild of 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	<p>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).</p> <p>Is the new content on medicine supply pathways clear and helpful? Why or why not?</p>	<p>The medicine supply pathways are clear and helpful along with the case studies. However, risk assessment is a factor that a pharmacist must consider before every compounding scenario. Hence, the Guild believes that inclusion of a risk assessment matrix in the guidelines would be useful for pharmacists to be able to follow a clear and concise pathway to assist them. In addition, if the tool in the guidelines is not suitable, then reference to the compounding decision support and risk assessment tool on PSA's Australian Pharmaceutical Formulary and Handbook (APF)² must be considered.</p>
2	<p>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.</p> <p>Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?</p>	<p>The Guild supports informed patient consent and believes that patients have the right to information about the medicines that are being supplied to them. The Guild agrees that providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. If requested by a patient, a pharmacist should provide the patient with a list of ingredients for the compounded medicine.</p>
3	<p>The revised compounding guidelines include content that is specific to medicines compounded for animal patients.</p> <p>Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?</p>	<p>The new content that is specific to animal patients is clear.</p>
4	<p>Is there any content that needs to be changed, added or deleted in the revised guidelines? If so, please provide your suggestions and reasons.</p>	<p>The Guild believes that the following should be considered for the revised guidelines:</p> <ol style="list-style-type: none"> 1. Inclusion of a risk assessment matrix for pharmacists to be able to follow or reference to PSA's APF risk assessment tool. 2. Include a case study articulating what Batch Compounding actually is and is not e.g. highlighting the following: <ul style="list-style-type: none"> • Can pharmacist compound several repeats all at once

² [Compounding decision support and risk assessment tool | Australian Pharmaceutical Formulary and Handbook \(psa.org.au\)](https://www.psa.org.au/compounding-decision-support-and-risk-assessment-tool)

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		<ul style="list-style-type: none"> • Can a patient who is on a regular compounded cream for many years, make a request for their cream to be compounded (in advance of a script), so they can collect the product when they drop off the script. <ol style="list-style-type: none"> 3. Case study 7 is missing. On page 11, case study jumps from 6 to 8. 4. Case study 8: Autism spelling is incorrect. 5. Inclusion of a case study where a pharmacy uses a third-party supplier to distinguish between compounding, depot arrangements and manufacturing.
5	Is the language of the revised guidelines clear and is the structure helpful? Why or why not?	The language of the revised guidelines is clear and helpful.
6	Please provide any other feedback about the revised guidelines.	<ul style="list-style-type: none"> • Clearer mapping of changes should be considered • The Pharmacy Board and Medical Board should consider a factsheet for prescribers consistent with the Pharmacy Board's compounding guidelines to ensure prescribers understand the professional obligations with compounded medicines. • Definitions for "supervising pharmacist" should be included. • Guideline 4: Facilities, equipment, working environment, materials, and support staff – The Guild recommends inclusion of the following clause: "All practice settings performing complex compounding should be accredited with a recognised quality assurance program." • Guideline 5: Formulation considerations – The Guild suggests expanding the statement to specify whether preparation of aseptic admixtures, preparation of products such as TPN, reconstitution of powdered vial via injection, are considered compounding for the purpose of the Guidelines.
7	The Board proposes to retire the <i>Professional practice profile</i> for pharmacists undertaking complex compounding, as a professional practice profile should be practitioner specific, describe an individual's	The Guild agrees with the Board on their decision to retire the current Professional Practice Profile for pharmacists undertaking complex compounding. The National Competency Standards for Pharmacists ³ addresses the requirements for simple and complex compounding. An

³ [National-Competency-Standards-Framework-for-Pharmacists-in-Australia-2016-PDF-2mb.pdf \(psa.org.au\)](https://www.psa.org.au/national-competency-standards-framework-for-pharmacists-in-australia-2016-pdf-2mb.pdf)

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	<p>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.</p> <p>Do you agree with the Board's proposal to retire the currently published <i>Professional practice profile</i> for pharmacists undertaking complex compounding? Why or why not?</p>	<p>individual pharmacist or an organisation should develop their own practice profile by customising them according to their own practice setting.</p>
8	<p>The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation.</p> <p>Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?</p>	<p>The Guild supports the intent of the factsheet and that it should be published. It may be a useful resource to explain compounding as a service and what it entails to people.</p>