. 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.

Please note this survey contains the same questions as the response template (Word document). Please choose only ONE method of responding to avoid duplicating your submission.

. Please provide your details below

Name	
Organisation name (if applicable)	
Contact email	

. **Published submissions will include the names (if provided) of the individuals and/or the organisations that made the submission unless confidentiality is requested.**

Do you want your responses to be published after public consultation?

- (●) Yes
- ( ) No

. **When providing feedback, please include the relevant guideline number/section that your feedback refers to.**

. 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)

Q1. 1. Is the new content on medicine supply pathways clear and helpful? Why or why not?

- term is confusing - The TGA comments to sponsors that SAS products shouldn't be used if the medicine can be compounded by a pharmacist for a specific patient https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-guidance-sponsors - The PBA and MBA both stating that only products on the ARTG should be considered as commercial and that products under SAS & S19A have not been assessed by the TGA also the MBA have not changed their statement on this https://www.medicalboard.gov.au/news/2017-11-24-media-release-joint-statement.aspx - The fact that allowing the SAS and S19A products to be on par with commercial products goes against the TGA and will affect the manufacturers who have spent the time and money in going through the correct ARTG route Our Compounding Pharmacy sources our Ingredients and APIs from High quality sources confirming the quality of oursourced raw material, where we get it from and the suppliers quality standards (TGA/GMP). Along with our own adherence to current guidelines (PBA/APF/QCPP/Safe work/state guidelines), we produce high quality compounded medicines as our patients safety is our primary priority ans has been for the last 20 to 30 years now as a compounding Pharmacist. o As opposed to SAS/S19A which may have standards outside the TGA - some potential language barriers on CMIs and leaflets from SAS products which may cause concern with care of patients and confusion. - Suggestion is to update this to make Compounding equal to SAS & S19A as we have been helping the Australian population for many years now with high quality compounded medicines.

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. 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.

Q2. 2. Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?

the fact a formula details not only all ingredients but also the steps on how to make the product. This could fall under copyright and Intellectual Property - Suggestion: that ingredient lists and ingredients of bases can be provided to patients when they ask

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. The revised compounding guidelines include content that is specific to medicines compounded for animal patients.

Q3. 3. Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?

this to be specific to a species not all types of animals

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Q4. 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.

- Content to be changed: o Refer back to question 1 around the definition of what should be included as a commercial product; an ARTG listed product

Q5. 5. Is the language of the revised guidelines clear and is the structure helpful? Why or why not?

very confusing sometimes, must be white or black, many grey areas which can lead to different interpretations.

Q6. 6. Please provide any other feedback about the revised guidelines.

not clear enough.

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. 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.

Q7. 7. 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?

. The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation.

Q8. 8. Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?

no, this process must between the Board and the Pharmacist as a join collaboration to enhance the quality of compounded medicines. we are working for one goal here: the safety of our public, hence Compounded medications play a crucial role to enhance people's health and help Drs resolve so many issues not fixed with commercial products.

. Thank you for your feedback. Please click on the NEXT button below to finalise your response.

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. 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)

Q1. 1. Is the new content on medicine supply pathways clear and helpful? Why or why not?

y

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Q2. 2. Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?

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Q3. 3. Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?

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Q4. 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.

Q5. 5. Is the language of the revised guidelines clear and is the structure helpful? Why or why not?

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This question was not displayed to the respondent.

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.

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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: [redacted]

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?**	**1.1.1 What is the role of the prescriber in medicines supply pathways? The onus here is on the compounding pharmacist. Prescriber knowledge about availability (or not) of commercial medicines (freely available, SAS or S19a) is important but lacking in practice. E.g., levofloxacin (SAS), rifaximin (freely available) – both items commonly requested to be compounded** **1.1.1 Who funds this process of consultation by the compounding pharmacist? Prescribers are becoming more difficult to contact / are unavailable / unable or decline to be contacted or respond. Why is the compounding pharmacist bearing the time-opportunity cost of the medication supply pathways? The end result may be no income for the compounding pharmacist by complying with best practice.** **+1.1.1 The guidelines do not consider affordability as a criterion for determining whether a medicine is suitable for compounding. "Cannot be accessed within the timeframe" could be due to solely to the patient not being able to afford the commercial product within the timeframe required. The proportion of people who delayed or did not get prescription medication when needed due to cost increased to 5.6% in 2021-22, from 4.4% in 2020-21 (https://www.abs.gov.au/statistics/health/health-services/patient-experiences/latest-release) In some cases commercial products exist (via wholesaler, SAS, S19A etc) but are not affordable to the patient however a compounded product may be e.g. melatonin MR 5mg. Proposed guideline 13 "recognise and respect the rights of patients to make their own decisions about their … healthcare" Where the choice is between no treatment (unaffordable commercial product) and affordable compounded product surely the patient could be supported to make an informed choice.**
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 should be able to access a list of ingredients in their compounded medicine UPON REQUEST. This should not have to be provided to each patient as it may not be relevant to their circumstances. Pharmacists should use their professional judgement in the same way this is exercised when deciding whether supply of a CMI is appropriate.**

	Question	Your feedback (include guideline number/section)
	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?**	
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?**	**New content does not add anything to information available through APVMA**
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.**	**5.2 Quantity to be supplied** **DELETE "If the quantity is not specified, this must be confirmed with the prescriber" Where is the responsibility of the prescriber? Again, who funds the compounding pharmacist to fix a lack of thoroughness on the part of the prescriber? Prescribers are becoming more difficult to contact / are unavailable / unable or decline to be contacted or respond.** **Many software programs used by prescribers (especially specialists) do not have a default quantity amount and many compounded items are prescribed "free text" which excludes prompts to enter a quantity s a compulsory data field. As such a number of prescribers do not specify a quantity or prescribe a quantity of "1". Some prescribers write max qty and max repeats. Surely as in the case of regular prescriptions written as 1 box or 1 tube the pharmacist can determine and supply a quantity sufficient for the treatment period. In this process the pharmacist should consider the expiry date of the compounded medicine. This should except the quantity of monitored medicines and Schedule 8 medicines should always be confirmed with the prescriber before supply.**
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	**No comment**
6	**Please provide any other feedback about the revised guidelines.**	**+In general, I feel the guidelines have covered the main issues in a satisfactory way.** **+It is good that "within the timeframe" needed is a factor to be considered when compounding. Other medicines pathways can result in**

	Question	Your feedback (include guideline number/section)
		a delay in treatment or uncertainty when treatment can commence which can be important. **+How will changes be communicated to the pharmacy profession? Recorded webinars, consultation, education options, FAQs resource would be suitable options accessible to all. This is a complex area and further instruction will be required for practical application. What support will be available for pharmacists who have questions about the guidelines?** **+An implementation period of minimum 6 months will be required before compliance can be assumed.** **+ALL pharmacists need to be encouraged to read the updated guidelines. Many will feel compounding is not relevant to them but almost all pharmacists in community pharmacy will need to manage "compounding" prescriptions (if only for referral purposes) and hence require a working knowledge of when compounded medicines are an appropriate choice.** **+How will these changes especially in the medicine supply pathways be communicated to prescribers of compounded medicines? It is not reasonable to expect compounding pharmacists to educate prescribers.** **+Will the joint Pharmacy Board and Medical Board statement on compounded medicines issued in June 2017 be updated and reissued?** **+ Batch preparation. Access to compounding services in remote and regional areas is difficult and evidence exists of poorer health outcomes for patients livings in these areas. Patients have often waited a long time for medical care and then face further delay when a compounded medicines is required for their treatment. Preparation in advance would be useful for these patients who could commence treatment on the day their prescription is presented (as is the case for commercial medicines). This would be cost effective for the patient (saving freight/postage), enable face to face counselling on the product, facilitate appropriate storage (e.g., fridge items) and improve outcomes due to early commencement of treatment.**

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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?**	**Yes – no longer required. Unnecessary duplication.**
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?**	**Yes. This would support pharmacists in explaining to patients the rationale for compounding and the differences to commercial medicines.**