. 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	Caleb Armstrong
Organisation name (if applicable)	Seville Village Pharmacy
Contact email	[redacted]

. **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?

The content on the supply pathways is clear but it is not always helpful. Compounding is a diverse activity and there are many situations which occur outside the parameters mentioned. Pharmacists are highly skilled individuals who take compounding seriously. I would suggest that confidence in pharmacists to make the best clinical decisions available in line with our training is important.

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

. 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?

Yes. No one should take medicine when they don't know what is in it.

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

. 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?

No. Veterinary compound regulations are not as clear as pharmacy guidelines which adds to confusion. Input from veterinary regulators may clarify this.

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

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.

Yes. Case studies should include both a negative and a positive outcome to clarify the difference between each.

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

The language of the guidelines express a negative context to compounding. Patients regularly have positive experiences with compounding and pharmacist are able to use their extensive qualifications to optimise outcomes for patients. It would be good for the language to express a balance of positive and negative contexts.

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

Compounding is often a great opportunity for increased cooperation between prescribers, pharmacists and patients. As such, it is a great way to increase an understanding of the role of pharmacists in the community.

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

. 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?

Yes

. 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?

Yes. communication and transparency are vital to positive outcomes for pharmacy and compounding

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

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: Craig Frawley

Organisation: MyCompounder Pharmacy Group

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?**	*I think it's a great improvement. Great job.* *One area which may have been missed is the area related to practice orders for compounded items for "in-clinic use". As an example, Dermatologists regularly order items for in-clinic use (e.g Cantharadin products for Warts or topical anaesthetic combinations for minor procedures) and Vets frequently order items for pre or post surgical use (e.g low dose trazodone to calm animals for consultations). Both clinician types are clearly empowered under the relevant Acts to order items for in-clinic use, and it would be great to see commentary about this to remove this practice a long standing "grey" area.*
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?**	I think its very reasonable to provide the list of ingredients when requested – specifically if there are allergies or potential intolerances to excipients.
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?**	I think its beneficial – to again highlight to various stakeholders that in the correct circumstances, that prescribing compounded medicines to animal patients is common and legal.
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.**	Yes. In my opinion, the need to "document" a risk assessment for each requested compounded medicine requires some clarification. Looking at our labs, over 60% of prescriptions presented are for drugs where manufactured equivalents of that drug exist on the ARTG, where the intended use of the compounded item for the patient is the same as the ARTG equivalents - but the drug is (typically) ordered in a smaller dose OR different dose form.

Formatted: Font: Italic

	Question	Your feedback (include guideline number/section)
		For example, omeprazole and melatonin for children, trazodone and gabapentin for pets, diazepam suppositories for muscle spasm and so on. The very existence of these drugs on the ARTG for specific indications, means that within reasonable dosing parameters, the drugs are safe. A written risk assessment should not be necessary. Secondly, in the absence of the above, where an assessment is completed for a novel drug or drug combination (common) and the prescription deemed safe, then this "risk assessment" should be documented within the pharmacy as a framework that pharmacists can read and overlay on future prescription presentations to accept or reject requests for compounding. So practically speaking, when presented with a prescription for a novel non-ARTG represented compounded item, Pharmacists would for example stamp the script, citing the relevant internal risk assessment form and either dispense or reject the prescription. This would be repeated for every original prescription and repeat prescription.
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	It is.
6	**Please provide any other feedback about the revised guidelines.**	See above.
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 I do. Its particularly relevant as most complex compounders actually tend to sub-specialise within compounding i.e become particularly adept in specific compounding areas – e.g Chronic Pain, Dermatology, Veterinary, bio-identical hormones, Cannabinoids and so on…. and will develop standards, career paths and education frameworks specific to those niches.

	Question	Your feedback (include guideline number/section)
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?**	Its perfectly reasonable.

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: Daniel Turner

Organisation: N/A – submission is being made in a personal capacity

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?**	**Yes, this new content should make it unambiguous to a decision-maker as to when it is appropriate to compound a medicine and reinforces their obligations in doing so.**
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?**	**Yes, having this information to hand to facilitate informed patient choice and better evaluate risks. It may also be pivotal if an adverse event occurs that requires medical intervention.** **There being zero provision for 'proprietary' or 'secret' formulas or ingredients in compounded medicines is key in distinguishing these from commercially available products that have been more rigorously assessed by the relevant regulatory authorities.**
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?**	**My contention is that veterinarians can also prepare compounded medicines and these guidelines should be considered best practise for anyone empowered to lawfully supply such medicines not just pharmacists.**

	Question	Your feedback (include guideline number/section)
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.**	**N/A**
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	**Yes, I found the revised guidelines to be clear and the structure helpful.**
6	**Please provide any other feedback about the revised guidelines.**	**Guideline 12 does not include any provision for an adverse event for an animal patient to be reported to the APVMA and/or to the relevant veterinary board. Whilst the Authority does not regulate compounded medicines, as they are not defined as veterinary chemical products, an active ingredient or an excipient might be associated with infrequent adverse events that an entity with a state/territory or national would potentially be able to spot from trends arising from such reports, which would otherwise not be on their radar.** **A specific example of this is the apparently widespread 'off-label' use of trazodone in the treatment of dogs in Australia, which it is well-established in the United States to cause paradoxical excitement in some cases. This human antidepressant medication hasn't undergone the efficacy and safety assessments associated with being a registered veterinary product, an animal owner advised that tablets prescribed to sedate their pet might be wholly unaware of there being any risk a dog could suddenly become aggressive. Trazodone isn't available in Australia as a TGA-registered medicine for a human patient, so has no labelled use *per se*.** **In the absence of a reporting system like that in place for reporting adverse events for human patients to the TGA, it seems shortsighted not to be advocating for a centralised repository of reports for animal patients. I note reports of adverse events are captured by the APVMA in case a sponsor subsequently applies to register a product that the contains ingredients or excipients linked to possible issues.**

	Question	Your feedback (include guideline number/section)
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?**	**N/A**
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 is a straightforward step that the Board should adopt in having information available.**

. 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	Des Harp
Organisation name (if applicable)	My Life My Health Compounding and Medical
Contact email	[redacted]

. **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?

The new content is clear but is not that helpful with the real running of a professional compounding pharmacy and the handcuffs being applied to an area or pharmacy that is supplying a very important service to the community. As long as we are not manufacturing our compounding medications there should be greater scope and different levels of compounders.

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

. 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?

yes i agree. we have been providing this for the past 15years i have had the business and can be easily done with the modern compounding software. should be done 100% of the time so the patient can scan for any ingredient that may not be right for them.

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

. 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?

yes, is clear and appropriate training or qualification should be held by the pharmacist if they can carry out Vet compounding. having different subspecialty areas for compounding would be a big help. each year the compounding pharmacy undergoes an audit and can be a self audit once the initial approval has been given then self audit with a renewal audit every 3-5 years.

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

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.

I think the whole guidelines needs an overhaul with separate subclasses added to complex compounding that must be initially approved then a self audit and fee done each year then another approval done every 3-5 years. The subclasses could be: Vet, Medicinal cannabis, paediatrics, Sterile, hormone, derm can add in other subclasses here. Then have subclass that meets the audited requirements to hold different levels of stock as i can see no increase risk to the public if the subclass requirements are met to hold compounded stock for on premise dispensing only. I am also a qualified chef and the requirements to hold a food licence (and the different subclasses) is a lot harder then what is currently set out in compounding in QLD other than just having to be a Pharmacist but over the years have gone into more detail and needs more defined qualifications similar to general pharmacy with Pharmacist prescribing, or vaccination etc to move forward into a subclass system.

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

the language is clear

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

See point 4 about different approved subclasses for complex compounding. An APP (may developed by APF) would be useful if a bud/expiry study has not be done that has inputs for stability of active, the base or dosage form and environment, preservatives add etc to assign appropriate expiry dates and storage conditions. Not that hard to work out once the research and parameters have been set in the app. We need the better use of technology being used in compounding. I also see the future of compounding evolving into a greater area for customized medications as the area of AI grows and health professionals as Doctors with the use of AI to better understand the human biology, genes and biomarkers to achieve greater health outcomes thus requiring non standard medications/supplements/lifestyle. AI will help health practitioners in the way a patient is therapeutically treated and I see a greater need for compounding services over the coming 5-20 years and having these subclass approved areas will see this area grow into the future with public safety health and safety at the forefront.

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

. 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?

I agree to retire the PPP for pharmacist but develop for ie: pharmacist who prescribe, vaccinate, plus all the other roles a pharmacist can do and subclasses of complex compounding is a great idea just writing them will be interesting but over time should produce a very diverse pharmacy profession!

. 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?

yes, should be transparent for the general public and pharmacist. especially for the difference qualification a pharmacist can have and future direction so the general public will know what to look for when seeking a complex compounding pharmacy that has been approved for each subclass. almost like the star rating given to food establishments. I have a food establishment and we obtained a 5 star rating. Just because you are a Pharmacist does not mean you should be able to compound! You must earn it!!

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

. 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	Dr Frank Sanfilippo
Organisation name (if applicable)	Complementary Compounding Pharmacy
Contact email	[redacted]

. **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?

It is clear. However, for the purpose of compounding, in Guidance 1.1 it would be more practical to keep the definition of “commercial medicine” limited to medicines that are listed in the ARTG. Medicines available through the SAS (and possibly through s19A) are not easily accessible for patients, and require paperwork (electronic or hardcopy) to be completed by the prescriber, with/without assistance from the pharmacist. This creates an additional workload for the prescriber, and pharmacists may need to check the current SAS status relating to the product requested for the patient. Hence, it would take longer for the medicine to be received by the patient, thereby creating delays in starting treatment. Compounded medicines prepared to a high standard would be more accessible and cost-effective to patients if “commercial medicine” is limited to its current definition only, and avoiding reference to other pathways such as SAS.

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

. 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?

Agree, but suggest more specific wording in Guidance 13 as follows. If a patient requests a copy of the formula for a compounded medicine they have received, then a list should be supplied by the pharmacy. The list should include: (i) active ingredients and strength; (ii) preservatives (if any) and strength; and (iii) inactive ingredients (strength is not necessary for these).

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

. 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?

Agree. This will provide guidance on use and safety in animals, and what pharmacists should consider when compounding medicines for use in animals.

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

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.

1. Guidance 1.1: definition of commercial medicine (see comments about this in Q1). 2. Guidance 13: add more specific details of what should be listed (see comments about this in Q2). 3. Guidance 7 (batch preparation): "…eg. a prescription has been received…" should be changed to "…eg. a prescription or prescriptions have been received…"

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

Language is mostly clear

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

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

. 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?

Yes agree. There are other professional pathways that allow us to prepare and manage our own professional competency for the practice of compounding. We can customise these to our own practice requirements. The Board's Professional Practice Profile would have to be too general and broad to cover all possible practice requirements and scenarios. Hence, it is best to leave this to individual pharmacists to manage.

. 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?

Yes it should. This will provide useful information for patients and the public. Perhaps consult with consumer representative/groups for input to ensure the language is understandable to the lay public.

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

. 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	Scott Myers
Organisation name (if applicable)	
Contact email	[redacted]

. **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?

Not overly clear, the difference between federal and state legislation by region is as clear as mud as usual. Saying that it is probably the best possible given the convoluted nature of Australia's health legislation that changes by region. We need the same document but catered for each state. The void between guidelines is dangerous and requires an immense amount of research to just abide by all restrictions.

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

. 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?

Yes; concentration of in-actives can be omitted so formula exclusivity is protected somewhat. The allowance of WA compounding to suddenly become proprietary and exclusive is disturbing however.

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

. 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?

Yes; a simple module can be completed to cover the pharmacist. The condition regarding the pharmacist managing food producing species feels difficult to manage [5.4]. This should be managed by the Vet entirely; consultation should be at request from Vet, especially if they are administering the product.

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

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.

Physicians need to be chased for receiving incentives for referrals to specific pharmacies. Currently nothing is done.

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

Yes, examples are particularly useful.

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

Consideration of PBS payments and the guidelines input needs to be in parallel. The time taken to perform the procedures required grossly outweighs federal funding for the same prescription. This difference will most likely result in shortcuts to retain profitability. $22.50 for a salicylic and glycerol cream provided on the PBS means that the entire risk assessment and compounding process must occur in less than 5 minutes at minimum pharmacist wage. The lack of realism in requirements and funding is a dis-service to all the patient protective instruction in this document. ie. do 30 minutes of work, yet we will only pay you for 5 minutes; this encourages rushed patient safety processes

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

. 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?

It's a very convoluted space, state based versions of this document need to be provided so it is easy to follow rather than a chore to sort through multiple documents all explaining things slightly differently.

. 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?

Of course it should. Is there any point in this document if that is not done?

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

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: Soo Luong and Robin Lee

Organisation: Central Pharmacy, Queensland Health

Disclaimer: The views put forward in this submission reflect the perspective of the authors as practising pharmacists in medicines compounding and quality assurance in a state funded pharmacy department and may not be taken as the representative opinion of the organisation.

Contact email: [redacted] or [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?**	Whilst AHPRA's intention for the inclusion of S19A and SAS as alternative medicine supply pathways prior to any decision to commence compounding may indeed be valid, the practical applications and future implications on supply chain, patient outcome, viability of compounding pharmacies and the pharmacy profession, as well as TGA resources require further consideration. a) **Global supply chain issues** – Over the past few years, Australian pharmacies have encountered unprecedented medicine shortages. A quick perusal of the TGA Medicine shortage reports database on 30/06/23 indicated that, there are 418 molecules of registered products which are currently unavailable with another 88 with shortages anticipated. Out of these, 48 were considered critical medicine shortage with another 11 shortages anticipated within this category. There were also 229 molecules being discontinued within the same reporting period, and 276 supply issues resolved. Due to its geographical isolation and with a relatively small pharmaceutical market, Australia will continue to be subjected to medicine shortages. COVID-19 had emphasised on the need for Australia to maintain its manufacturing capability including for pharmaceuticals. Although technically not considered a manufacturing activity, quality compounding will ensure that Australians have timely access to urgent, critical, quality medicines when they need them, at an affordable cost. b) **Impact on patients** - **b.1: *Treatment Delays* -** S19A and SAS medicines are not readily available from current pharmaceutical wholesaler and are not subject to the wholesalers' Commonwealth Community Service Obligations (CSO). Most community pharmacies (compounding or not) simply do not have the experience, knowledge, time, and staffing resources to undertake sourcing activities, within a timely manner. Furthermore, for most regional and small business pharmacies that are

	Question	Your feedback (include guideline number/section)
		sole pharmacist operated, there may not be any supporting resource for this sourcing activity. Hence, rather than spending precious time ensuring the quality compounding of a product for the patient, they will instead unnecessarily waste that same time performing sourcing activities with no real positive outcome for the patient, resulting in treatment delays potentially resulting in adverse outcomes. From our experience as a state-own pharmaceutical wholesaler, Central Pharmacy had encountered many sourcing challenges over the past few years, not only for registered pharmaceuticals, but unfortunately also for S19A and SAS products. As a state own compounder servicing Qld Health network of hospitals and health services, we can also attest to the excessive wait time for information (including price and Product information) from our S19A/SAS suppliers as well as delivery delays. These significant, protracted turnaround time had resulted in multiple requests for the in-house manufacturing unit to provide a "stop-gap" measure to ensure continuity of treatment for the hospital patients. ***b.2: Brand Bioavailability/Formulation variance*** S19A and SAS products do not always have the same bioavailability (and hence same clinical outcomes) as their registered counterparts. Some of these products unfortunately, do not have Product Information in English. From our experience, there are also significant variations in presentations, excipients and prices between different S19a/SAS products with the same active ingredients. AHPRA has proposed that compounding pharmacies have an obligation to "share" their formulation with their patients to ensure continuity of treatment. Unfortunately, it's well known that for some products with narrow therapeutic index or with complex formulations eg Tacrolimus suspension, different brands do result in different patients' outcomes.

	Question	Your feedback (include guideline number/section)
		SAS suppliers are not in a position to provide timely and professional advice to community pharmacists regarding safety and efficacy of the SAS formulations during sourcing activities. Although professionally trained compounding pharmacists have the skills and experience to review SAS formulations, the full lists of ingredients and strengths are not always available from the overseas manufacturers. This contrasts with a compounded product where the pharmacist has full knowledge of the formulation for assessing the product's safety and suitability for the patient. Australian health professionals and consumers are familiar with generic prescribing and hence most are comfortable to have their medicines substituted with different brands. Unfortunately, whilst TGA and PBS have done their due diligence in conferring "brand substitution" permission to registered molecules, S19A and SAS products are not similarly assessed. For the less informed health professional and public, complacency in "brand substitution" of SAS products may result in patient harm. Most prescribers would not undertake to prescribe non-registered products unless absolutely, necessary. However, most simply will not have time to continually navigate SAS paperwork or identify a suitable SAS alternative. Therefore, this will result in additional impost on time and resource poor pharmacists. It's also virtually impossible for AHPRA to monitor which compounding pharmacists had undertaken sourcing activities for S19A/SAS products prior to embarking on a decision to compound. b.3: ***Patient referral to State Public Hospital System*** The challenges and difficulties in sourcing and assessing SAS products encountered by community pharmacists will result in increased referrals of patients to the State funded public hospitals system for access and supply of non-TGA registered products, as well as for secondary care due to delayed in treatment and worsening of primary conditions. These will result in further healthcare burden on

	Question	Your feedback (include guideline number/section)
		the state facilities. b.*4:* ***Medication compliance*** The revised guidelines propose that pharmacists must not compound a medicine containing more than one active ingredient if a combination of commercial medicines including SAS medicines are available. The use of a single dosage form comprising multiple molecules in fixed dosage is an established way to facilitate dosing compliance as it is not necessary for patients to take multiple separate medicines, Compounded dosage forms containing more than one medicine will benefit patients who are on polypharmacy and on stabilised dosages. Applying a blanket rule that pharmacists should not compound medicines containing multiple medicines when separate commercial medicines are available does not take into consideration medicine compliance challenges faced by the patients. **b.5:** ***Cost of Medicine access*** The revised guidelines also stipulate pharmacists not to compound a medicine even it can be offered as a lower priced alternative than a commercial SAS product. With costs of living issues confronting the Australian public and the Government's focus on reducing cost of access to medicines, the revised guidelines as it stands appears to be contrary to these government initiatives. As an example, until recently, there is no TGA registered Omeprazole Suspension, our state-owned compounding centre has been compounding the product based on the APF formulation supported by inhouse laboratory research data and published literature for supply to state hospitals for almost a decade. Likewise compounding pharmacies have also been compounding formulations to meet patient requirements. Although a commercial product is available in the UK, the imported price as an SAS product is more than double the cost of local compounding, representing an unnecessary cost burden on the patients. **c) Impact on Compounding pharmacies and the pharmacy profession** – Whilst there are inherent risks and

	Question	Your feedback (include guideline number/section)
		quality concerns with pharmaceutical compounding, such risks can be reasonably managed by sound quality management principles. We believe the majority of pharmacists registered in Australia are professional and skilled, with conscientiousness to capably meet patient needs. As with most professions, there will be "rogue" operators who choose not to follow TGA and AHPRA compounding quality guidelines. Rather than restricting the criteria to compound, AHPRA should focus on how to address these "rogue" operators to ensure that patients in Australia receive the care they deserve. Compromising the viability of compounding pharmacies through these proposed revised guidelines, may have the unintended long term consequences of decimating the industry, resulting in future loss of investment in infrastructure and professional upskilling for our pharmacists within the compounding sphere. The reality is that in its proposed form, compounding is relegated to a "last" option for patient treatment in the absence of TGA registered, S19A or SAS commercial pharmaceuticals. The consequence of this would be that disheartened compounding pharmacists may exit the market since maintaining an acceptable compounding facility with suitably trained staff requires investment in professional dedication, time and efforts. It' s not viable for compounding pharmacies to commit these professional undertakings if their main source of income is from labour-intensive, non-profitable, semi-professional S19A/SAS sourcing activities. In recent years, the pharmacy industry had encountered many business viability challenges including the recruitment and retention of professional staff and this latest proposal may further worsen the situation. d) **Impact on TGA resourcing and registration of pharmaceuticals in Australia** - AHPRA had stated that the revised guideline is to safeguard the pharmaceutical industries' drug development and approval process.

	Question	Your feedback (include guideline number/section)
		Not all S19A and no SAS products have been stringently assessed by the TGA as having equivalent clinical benefit as unavailable TGA registered pharmaceuticals. During periods of significant medicines shortages, TGA has undertaken to assess medicines through the S19A pathway. However, these processes take time and only undertaken by TGA in the event of severe, ongoing shortages with significant adverse patient impact. TGA serves as a national "gatekeeper" for medicines into Australia. TGA licensing and subsequent product registration incur significant costs, time, resources and efforts. Australia through its PBS price reduction and price disclosure strategies, as well as being geographically isolated with a relatively insignificant market, already had many registered products unavailable in recent years. Some of these products were unavailable for a period before being discontinued by their sponsors/manufacturers. Ironically, these discontinued molecules continue to be available overseas eg Avastin™ (SAS), whilst the Australian registered Avastin™ had been discontinued since 2021. This SAS product is currently more than twice the price of the discontinued Australian-registered Avastin™. Through this proposed, alternate medicines supply pathway, apparently interpreted as a superior alternative to compounding in Australia, sponsors and manufacturers of S19A/SAS are "assured" of the continued sales and profitability of their "discontinued/deregistered" products (which are ironically exorbitantly priced compared to their discontinued equivalents, as documented above). Under the current proposed Compounding Guidelines, SAS products without undergoing the corresponding rigours and efforts associated with maintaining TGA registration would still enjoy the privilege of preferred sourcing. This may result in the unintended consequences of disincentivising manufacturers to register their products within Australia,

	Question	Your feedback (include guideline number/section)
		This may then also result in significantly more registered products being discontinued in Australia in future, creating a vicious cycle of supply chain issues. e) **Pharmaceutical raw ingredients suppliers** – the viability of these suppliers would be significantly impacted if SAS products are prioritised over compounding as an alternate pathway. Pharmacies have weathered many uncertainties over the recent years, especially worsened by COVID-19 impact on global supply chain including for raw ingredients and consumables. Suppliers are struggling to maintain "business as usual (BAU)" due to all the certainties around the world. We have witnessed an unprecedented number of shortages over the past few years, including that of common antibiotics such as amoxycillin and cefalexin. The Board needs to seriously consider if decimating rather than regulating the pharmaceutical compounding industry is the best way forward to ensure positive patient outcome. From experience, Central Pharmacy can attest to regular shortages of previously commonly available raw ingredients. The Board's decision to prioritise SAS as alternate pathway above compounding will render most raw ingredients ultimately too expensive and/or too inaccessible. With all the uncertainties around the world, it's inconceivable that the Board would seek to introduce more uncertainties to the pharmaceutical supply chain. Whilst undeniable that "rogue" operators will exist in all industries, for the most part, patients have benefitted significantly from the services offered by compounding pharmacies
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.	This is a sound proposal however as articulated within 1-b.2 above, it would appear to be inconsistent with the intent for the recommendation to prioritise S19A/SAS over compounded products

	Question	Your feedback (include guideline number/section)
	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?**	Most compounding pharmacies have a mix of human and animal patients. Adoption of any guidelines impacting the viability of compounding pharmacies will result in adverse outcome for the animal patients
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.**	a) To **retain** Professional Practice profile within the proposed guidelines – please refer to feedback for Q7. b) To remove the recommendation that SAS products are to be prioritised above compounded pharmaceuticals. Whilst S19A products are somewhat scrutinised by TGA, most SAS products are not. Currently, TGA is not likely to be sufficiently resourced to be able to scrutinise and monitor for the quality and availability of imported SAS products. Whilst TGA maintains an oversight web portal for Medicines Recall and Medicines Shortage of registered pharmaceuticals, there is no such portal for SAS imported medicines. The different categories of SAS products may also inadvertently result in unsuitable SAS products being used on patients. .
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	**In the Draft revised guideline 1.1.1a, there is provision to:** **"compound medicines in circumstances when an appropriate commercial medicine does not exist, is unavailable or cannot be accessed within the timeframe that the medicine is required for use by the patient"** This is an ambiguous statement at best and once again, imposes on the pharmacists to assess "clinically" what is considered a suitable timeframe for an S19A or SAS product. The time taken for the pharmacists to assess this with the patients and prescribers as well to explore S19A/SAS alternatives is not reimbursable.

	Question	Your feedback (include guideline number/section)
		Trained, professional compounding pharmacists will provide better quality care to patients by focussing on compounding activities rather than these potentially fruitless exercises.
6	**Please provide any other feedback about the revised guidelines.**	The proposed, revised guidelines appear to have been drafted with minimal consultation with relevant stakeholders including prescribers (Doctors and Vets), patients accessing compounded products, S19A and SAS suppliers, pharmaceutical raw ingredient suppliers, state hospitals, pharmacists, and other relevant stakeholders. The complexity of global sourcing issues appeared not to have been taken into serious consideration when these revised guidelines were drafted. Positive patient outcome should result from better monitoring/auditing of compounding practices within pharmacies as well as more comprehensive professional practice framework with industry accepted quality management principles and standards for adoption. We propose that AHPRA extend the public consultation period and actively send out information to all relevant stakeholders to ensure that patient outcome is not compromised. . The Australian public and health professionals' interests should be safeguarded in practical, cost-efficient manners.
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?**	**We disagree with the Board's proposal to retire the currently published *Professional practice profile* for pharmacists undertaking complex compounding.** We believe the way to ultimately safeguard the patients' interests is to ensure that health professionals undertaking professional activities do so within a documented comprehensive professional framework, which form the basis of minimum competencies required for their practices. USP 795, USP 797, PiC/s PE009 and PE010 all have documented minimal requirements. Although undoubtedly, all professionals (health or otherwise), may develop their personalised practice profiles, there should be a minimum standard for the various scope.

	Question	Your feedback (include guideline number/section)
		If the Pharmacy Board is really keen to ensure quality within the compounding sphere, as well as positive patient outcome, retiring this Professional practice profile will achieve the opposite effect. AHPRA (Pharmacy Board) had been tasked and trusted by health professionals and the public to ensure professionalism of the various health professions under its umbrella.
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?**	Which fact sheet will be published and when? After the deadline of 24/07/23, will there be another round of public consultation where the Board intend to publish the fact sheet? As per item 6, we do believe the public and the wider health profession need to be informed about this upcoming revision so they may participate during its consultation. Depending on the contents of the fact sheet, we are in favour of its publication since patients whose health and interest we are looking after should have sufficient background information to contribute meaningfully to this discussion since they will be most affected.

. 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	STANLEY SEEHO
Organisation name (if applicable)	CustomMed Compounding Pharmacy
Contact email	[redacted]

. **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?

Section 1.1 , No. 1. Section 1.1 NO The reason the ARTG is there is to ensure that commercial medications meet standards before they are included. If all medicines can be accessed via SAS then what is the point of the ARTG. If the doctor prescribes a medicine and it is accessed via the SAS who is responsible or liable if an adverse reaction or worse happens- the doctor or the pharmacist? Who is responsible for the quality of an SAS accessed product if the ARTG has not approved it? Does the pharmacist have to inform the doctor of every single item that can be accessed via the SAS? Where does the pharmacist get this information? Who will educate doctors on when they need an SAS or when they can write a simple prescription? Will the Board be educating all GPs and Specialist of these changes and also how to access the SAS scheme? Also Compounded products are made individually for a specific patient and to treat them in a particular way and dosage that is optimal for them so the doctor or the patient in consultation with the pharmacist should decide which is most appropriate or them. With most compounded products the active ingredient is exactly the same dosage as a proprietary product and will produce the same efficacy so I see no advantage in using a Non-ARTG approved product through the SAS.

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

. 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?

2. Section 4.2 NO. Formulas should not need to be released to patients. 1. It is intellectual property and the sole right of the compounder. 2. The ingredients list is sufficient to ensure any compliance to allergies and adverse reactions. If the pharmacist is not satisfied they can compound a particular medicine they will refer the patient to one that is. 3. There is no compulsion on registered products to release their formulas. 4. The registered products don't even have simple information such as pH or quantities of each ingredient-why should pharmacists? 5. It adds an extra level of complication and cost to the compounding service. 6. Is there a commitment to a pharmacist that if he releases the formulation that the patient MUST get that medication from that pharmacist alone? 7. Does the patient have to sign a Non-Disclosure Agreement before the formula is released? 8. Who is to police the release of formula if the patient takes it and goes to another pharmacy? 9. What happens when there is a problem with the medication? Is it the originator pharmacy or another that used that formula and did not do it exactly the same? I have had spaghetti made by two cooks using the same recipe and one will taste better than another.

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

. 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?

yes

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

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.

I have already made suggestions

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

No. Also I had to search the website a few times to get the right document

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

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

. 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?

yes

. 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 opinion

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

. 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	Youssef Takla
Organisation name (if applicable)	[redacted]
Contact email	[redacted]

. **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?

1 When to compound medicines - Guidance 1.1 Considerations before compounding a medicine The content is not clear and certainly place more liability on the pharmacist while the responsibility stems from the prescriber the reasons detailed below; Prescribers often find the SAS pathway to be too troublesome, with many of them are not willing to spend time and undertake the steps needed to obtain approvals. There are multitude of other reasons to why prescribers don't elect to undertake the SAS application route; such as the use of the medication for conditions other than commonly intended (off label) with application unlikely to be approved, or when the patient need the medication in a timely manner and cannot afford to wait for the approval of the application. Prescribers needs to be educated on SAS medication lists and how to access them for their patients if they qualify, however, it is not the pharmacist role or responsibility to do so. The pharmacist's role can be limited to alerting the prescriber and/or the patient of the available SAS option. Shall the prescriber disagree on undergoing the SAS pathway, the pharmacist is not encumbered to compound the requested medication, and certainly cannot be deemed liable for compounding the requested preparation. The compounding pharmacist shall bear no responsibility with respect to the prescriber's decision for the compounded medication in this case. The wording of "must" in this sentence, needs to be downgraded to "should" at best for scenarios concerning SAS pathway "Consultation with the patient (or their agent) and their prescriber must occur when other supply pathways are more appropriate than compounding."

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

. 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?

Guidance - 13 Supporting informed patient choice Yes, there should be no issues supplying the full list of ingredients to patients ONLY when requested. Including the full list of ingredients on every compounded preparation will be cumbersome to both the pharmacist and patients. Supplying the full list of ingredients will not be an issue if the pharmacist has the full list of ingredients for the compounding vehicle base that they use, or if they compound the vehicle itself, however, there is a clear issue with compounding pharmacy suppliers who don't offer the full list of ingredients in their preparation. Most of the pharmaceutical compounding bases are not regarded as medical or therapeutic products and their packaging or SDS doesn't reflect the full list of ingredients, and in most cases, it would only state "proprietary ingredients". The board needs to acknowledge this issue and address it with major compounding base suppliers including but not limited to Medisca, Fagron, Humco, and Letco, before the pharmacist could be expected to be able to provide a full list of a preparation that they made using a branded compounding vehicle base.

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

. 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?

Clear

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

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.

"1.1 Considerations before compounding a medicine, Consultation with the patient (or their agent) and their prescriber must occur when other supply pathways are more appropriate than compounding." The liability and responsibility in this situation cannot be on the pharmacist. The pharmacist should not be forced to be contacting the prescriber in this case. The word choice of MUST is not appropriate as the primary responsibility falls on the prescriber. It is the prescriber's job (to put it in simple terms) to investigate the medication options before they decide on prescribing a compounded item. The wording in this phrase needs to be "SHOULD" instead of "MUST". Pharmacists have plenty of responsibilities at their hands as is. Pharmacists contact prescribers on daily basis to obtain the best patient's health outcome. While there is NO harm to the patient from the presented script, the pharmacist should not be forced to contact the prescriber to discuss their prescribing choices. The information can be conferred to the patient whom can ultimately contact their prescriber and be informed of their treatment decisions. Very regular occurrence, the prescribers don't return pharmacists' calls or emails, who bears the responsibility of a patient's adverse effects or worsening of their disease while the pharmacist is waiting back to hear from the prescriber? Whether the pharmacist elect to compound the script or not, is their professional decision, however, they are not required to undertake all those additional layers of work in this instance. Most pharmacists will offer their assistance in such situations; however, they cannot be compelled or obligated to. Educating prescribers of the SAS options and process is not the role or the responsibilities of the pharmacist nor is the pharmacist funded to do. This is an example that I will use twice through my submission; A pregnant lady presents with a hospital ED script for Nifedipine 20mg tds for prevention of preterm delivery. Nifedipine is soon to be available as 10mg capsules on SAS. Would it be appropriate for the pharmacist to halt compounding the script pending contacting the prescriber and alerting them on the SAS option? Would it be appropriate for the patient to wait while the TGA decide on the application for the SAS? Shall the pharmacist reject compounding the script in this case as SAS is deemed as a more appropriate pathway? Who would bear the responsibility if patient deliver prematurely while the pharmacist was waiting to hear back from the obstetrician/prescriber? There are too many examples of similar scenarios. "Starting materials: • Pharmacists sourcing starting materials from a third-party supplier, including a wholesaler, are responsible for confirming the manufacturer has an appropriate licence, certificate or equivalent accreditation." The pharmacist cannot bear responsibility with respect to a starting material being any different to the CoA provided by an Australian-based third-party chemical supplier or compounding wholesalers. Most compounding pharmacies don't have access to analytical testing equipment and have to rely on the CoA provided by the handful of Australian-based compounding wholesalers. The board also needs to clarify what are the 1. appropriate license, 2. certificate, or 3. equivalent accreditation, that are being referred to in this paragraph. The term of "TGA approved" is used commonly without base. For example, a contract manufacturer who obtained a basic manufacturing approval from the TGA doesn't mean they have the proper license or approval to repackage and resell compounding chemicals in Australia. This much needed guidance needs to be provided to Australian pharmacists undertaking compounding services. Regulatory government bodies such as the TGA need to police and audit the handful of chemical suppliers and compounding wholesalers supplying chemicals to Australian compounding pharmacies. "If a certificate of analysis (C of A) is not available for an ingredient or not provided by the manufacturer, or the pharmacist has concerns about the authenticity of the C of A, the pharmacist should have the ingredient tested by a laboratory holding appropriate credentials for testing (e.g. accredited by the National Association of Testing Authorities (NATA) or licensed by the TGA), to confirm its suitability for compounding." Again, The board needs to give proper guidance and refer to external source where a pharmacist can find a list of NATA accredited, or TGA approved laboratory that are willing or provide services of testing chemicals and verifying CoAs. There also needs to be a reference to the exact 1. appropriate credentials for testing, and/or 2. specific TGA or equivalent license(s) that such laboratories need to have for them to qualify for testing of pharmaceutical chemicals for compounding use. We find the term "licensed by the TGA" to be quite vague and leads to lots of assumptions. "5.5 Consistency of Supply If requested to compound a medicine that has been previously compounded by another pharmacist and/or at another pharmacy, the pharmacist must take reasonable steps to assure themselves that the requested medicine has been compounded consistently with previous supplies by using a formula is as close as possible to those used previously unless there are quality or safety concerns about the previous compounding. Changing the formula from that of previous supplies could result in changes to the clinical effect of the medicine and have consequences for the patient. Consistency in formula is particularly important for high-risk medicines such as those with a narrow therapeutic index, or for modified-release preparations." This will be hard to implement, especially with the myriads of fillers, inactive ingredients and different grades of the chemical inactives used, let alone different vehicle bases available by different suppliers. For example, a compounding pharmacy who doesn't hold membership with PCCA, and cannot purchase the same PCCA proprietary base that the previous pharmacy used to use as a vehicle for a certain preparation. The responsibility of the compounding pharmacist should be limited to advising the patient that compounding preparations cannot be identical between pharmacies, and inform them of all the implications that can follow. The patient will need to decide whether they would option to continue with their old pharmacy that used to compound his/her medication or go ahead with the new pharmacist. The patient (In line with 13. Supporting informed patient choice) can request a full list of ingredients from his previous pharmacist, share it with the new pharmacist, and only then the new compounding pharmacist can decide whether they can compound a similar preparation or not. It is worth noting that there is a degree of variation between different brands for many narrow therapeutic index that are commercially available and not only compounded medications. "A medicine (whether prescribed by an authorized prescriber or not) should not be compounded if: 1) a commercial medicine is a suitable treatment option for the patient, or 2) 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" The term of "Unlikely to produce a different therapeutic outcome" is quite vague and will be difficult to gauge. How can it be measured and who would bear the extend of liabilities that may arise from the dose change? There are many examples and scenarios that clinicians would have different views on. Nifedipine 20mg tds for stopping preterm delivery. Would Nifedipine 30mg SR tablets bd be "unlikely to produce a different therapeutic outcome?" Who would bear the responsibility if patient deliver prematurely while the pharmacist is waiting to hear back from the obstetrician? Or If the obstetrician followed the pharmacist advice as the change of dose seems unlikely to produce a different therapeutic outcome, and the patient deliver prematurely?

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

Language is clear with except of some vague statements such as "Unlikely to produce a different therapeutic outcome"

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

In our views the revised guidelines add significant liabilities on the compounding pharmacists, while in many scenarios, the liabilities lie with other parties such as prescribers, patients, and compounding wholesale suppliers.

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

. 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?

Neutral opinion

. 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?

The fact sheet -assuming to be attachment C of the guidelines- only refer to TGA registered medications and compounded medications, while the actual guidelines explicitly refers to the SAS pathway.

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