. 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	[redacted]
Organisation name (if applicable)	ASCP – Australian Society of Compounding Pharmacists
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 pathway is an improvement on existing guidance but there has been the added complication and in the definition of where S19 and SAS medicines sit, compared to the compounding of medicine option. Currently the TGA does not recognised S19A and SAS medicines as registered commercial medicines as these do not exist on the ARTG. With the current working of the compounding guidelines, it appears that there is a preference in pharmacists considering/using SAS and S19A medicines, before considering compounded medicines. This could have unintended consequences for Patients and Pharmacists. In the current pharmacy environment the SAS and S19A medicines require shipping from overseas locations, via an Australian sponsor, then to the pharmacy. These shipping delays will result in patients having a significant delay to their therapy. The TGA Guideline for Sponsors of SAS Medication recognises a compounded preparation should be considered as an option before SAS. The other consequence is that Pharmacists will see (through the publication of these guidelines) that the compounding of medicines is an inferior option for patients and no longer consider it. Our suggestion to remove the existing wording in 1.1 below: 'and medicines accessed via pathways such as s19A, Special Access Scheme and others' The paragraph will then read "For the purposes of these guidelines a 'commercial medicine' is a medicine on ARTG which has been assessed by TGA for safety and efficacy. Medications accessed via SAS and S19A and a medicine compounded by a pharmacist are unapproved medications which are not "commercially available".

. **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?

While we agree with guideline 13, ASCP believes the requirements for the provision of information should be consistent to requirements or sponsors/manufacturers and their ARTG medicine information requirements. A formula is different to list of ingredients since it includes preparatory instruction and concentrations of active and inactive ingredients. ASCP believes the patient must have access to the list of active ingredients and their concentration, as well as a list of inactive ingredients (without the concentration) in their compounded preparation. This would be in line with the list of ingredients provided in CMI of a commercial product.

. **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, ASCP agrees that there is value in adding this section regarding compounded medicines of animal patients. We suggest a change in term from ‘type of animal’ to ‘species’.

. **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.

No.

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

Yes.

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

ASCP has three final questions: 1. Will there be a phase-in period for the implementation of the new guidelines? This should be in place to assist pharmacists in reviewing their existing practice and operation and undertaking necessary changes to meet the new guidelines. 2. How will the rollout and commencement of these guidelines be communicated? A recorded webinar would be a fantastic option for those pharmacists who are currently time-poor. We acknowledge that plenty of significant challenges are occurring in the pharmacy industry. 3. How the new guidelines will be communicated to the doctors? No other comments

. **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, ASCP agrees that the practice profile should be retired.

. 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, ASCP agrees that a published fact sheet (for Pharmacists and the Public) should be available. This will assist in giving practitioners and members of the public confidence in using compounded medicines. ASCP believes updating the existing FAQ and factsheet to reflect the new compounding guidelines would also be necessary.

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