Guidelines on compounding of medicines review - response template

The Pharmacy Board of Australia is inviting feedback on its draft revised *Guidelines for compounding of medicines* (the draft revised guidelines). Optional questions have been provided below and you may wish to address some or all of these in your response.

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

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

☒ Yes, I want my responses to be published after public consultation

☐ No, I do not want my responses to be published after public consultation

Submissions for website publication should be sent in Word format or equivalent.[1]

Name: [redacted]

Organisation: _____PCCA _____

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?**	We believe that the medicines supply pathway needs some further clarification in the proposed guidelines. While we do recognise that particularly since the Covid pandemic that there are many drug shortages, medicines provided via SAS or s19A may not always be available. Compounding pharmacists should be aware of these other pathways and be able to discuss all options with both the patient and the prescriber. However, in many cases the supply may be limited to one wholesaler, the information for the product may not initially be available (e.g. the original information is not available in English in the first instance and the pharmacist must request translations etc) or the product itself may also have excipients which are not suitable for the patient. It seems difficult to define exactly how much time and effort a pharmacist is expected to dedicate to navigating these pathways particularly when very often the prescriber's themselves have little or no idea about how to access the appropriate SAS forms, let alone how to complete them. In many cases even though a product may be available through SAS or s19A, patients report that it is "not the same" as the registered product which is currently unavailable. Some of these patients have tried a compounded product and report that they get better results with the compounded product and prefer to use that. In some cases, of course, the use of an SAS or S19A product may be more suitable e.g., if the raw materials cannot be accessed for compounding. In other cases, however, the opposite is true e.g. consider the case of a patient where English is not their first language who has been prescribed a medication which could be filled by SAS or equally via compounding. Explaining to a patient who already has a prescription that now they have to wait until the pharmacist contacts the prescriber to apply for SAS would become almost unmanageable for both the patient and the pharmacist.

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		Overall, we find it difficult to understand why the proposed guidelines have expanded the definition of "commercial medicine "to include S19A and SAS, but do not include compounding. Previously, when discussing the appropriate use of compounded medicines e.g., in the Pharmacy Board and Medical Board of Australia Joint Statement on compounded medicines (24 November 2017) the Pharmacy Board states that: "Unlike medicines ***on the Australian Register of Therapeutic Goods (ARTG)***, compounded medicines are not subject to rigorous assessment for product efficacy, quality and safety by the Therapeutic Goods Administration (TGA), and therefore additional considerations are required" and that, "A pharmacist who receives a request to prepare a compounded medicine for which there is a close formulation to a suitable medicine ***on the ARTG*** and which is unlikely to produce a different therapeutic outcome to the ARTG medicine should consult with the prescribing medical practitioner regarding alternative treatment options. To that end, the original (v1.0) of the Guidelines on Compounding of Medicines under "Section 15 Counselling and Information for Patients" state that the pharmacist must counsel the patient including "an explanation of why a compounded product is being supplied and how this differs to a ***commercially-available medicine which requires the manufacturer to meet the requirements of the TGA for addition of medicines to the Australian Register of Therapeutic Goods***" Neither SAS nor s19A appear on the ARTG and are only approved because there is" both a shortage of a medicine registered in Australia and the medicine is needed in the interest of public health." While the Pharmacy Board has considered it appropriate to consider SAS and S19A under the umbrella of "commercial medicines" this appears to be at odds with TGA guidance outlined for sponsors and health practitioners. In the TGA document "Special Access Scheme (SAS) Guidance for Sponsors (v1.1 March 2023, page 5 of 17) states describes "when the SAS is not appropriate" stating that "the SAS should not be used when-

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		• Product is in the ARTG and available for supply in Australia, including for off-label use. • Medicines …are extemporaneously compounded by a pharmacist for the treatment of a particular patient. • There is a current section 19A approval in place for supply of an overseas medicine during a shortage and stock is available. In the TGA document "Special Access Scheme (SAS) Guidance for Health Practitioners accessing unapproved therapeutic goods the health practitioner is advised that before prescribing an "unapproved" therapeutic good, they must consider several pathways including considering risks of treatment, so this same risk assessment must occur for SAS and extemporaneously compounded products. This document also states that the health practitioner is responsible for deciding which pathway is appropriate, and that their patients must be able to make an informed decision. Overall, it is our considered opinion that medicines , in particular those accessed via SAS, may carry with them just as much risk as extemporaneously compound medicines. **The phrasing of Commercial medicine in the Definitions (page 30of 32) states-** "**Commercial medicine** means for the purpose of these guidelines a medicine that can be accessed in Australia through any pathway for the lawful supply of medicines". The fact that extemporaneous compounding is allowed through an exemption under the Therapeutic Goods Act means it IS lawful. ***To that end, we would like the Pharmacy Board of Australia to reconsider their definition of "commercial medicines" and revert back to defining a "commercial medicine" as one which has been assessed by the TGA and appears on the ARTG, which then categorises all other medicines accessed via SAS, s19A and extemporaneous compounding at the same level of "unapproved" therapeutic goods.***

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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?**	As part of the *risk assessment process*, it is the pharmacist's professional obligation to gather as much information about the patient's specific allergies etc in order to prepare a safe and efficacious product. This is the opportunity for the pharmacist to assess whether the formulation they plan to use is appropriate for the patient (including flavours, preservatives etc) However, even with the best intentions there are often unanticipated situations where a patient may be allergic to either an active ingredient or an inactive ingredient of which they were not previously aware. We agree that it is appropriate for the pharmacist to provide information about active ingredients (and their strengths) and inactive ingredients on patient request. This aligns with information provided by sponsors of ARTG listed medicines on their CMIs.
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?**	1. In the labelling section the guidelines require the label intended for veterinary medication to specify the "kind' of animal. We would suggest that a better phrase should be "species" of animal. 2. In section 5.2-Quantity to be supplied In the "Note for animal patients" it suggests that "a pharmacist may supply more than a single unit of issue……." While we do not object to this statement per se, one of the big issues around compounding for animals is that in many situations the vet will expect the medication to be supplied to the veterinary surgery where the vet often supplies it to the patient (and charges them for this). We are concerned this statement may lead pharmacists (and vets) to believe that they are able in general to supply compounded medication in bulk, which might in turn suggest batch compounding in anticipation. 3. There are TGA links which advise pharmacists of current and anticipated medicine shortages. Has the Pharmacy Board discussed with the APVMA whether they are able to provide a similar link where

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		pharmacists can confirm whether there are veterinary medicine shortages.
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.
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	We consider the language to be appropriate for the pharmacy profession.
6	**Please provide any other feedback about the revised guidelines.**	• We believe it would be useful to have some communication from the Board about the manner in which these guidelines will be rolled out to ***prescribers***. It is a very daunting situation for pharmacists, already under pressure to meet their professional obligations as outlined in the Guidelines to then have to explain many times over, to many prescribers about the "decision -making cascade" which the prescriber should consider before prescribing a compounded medicine. While most pharmacists regularly attempt to contact prescribers, many report that it is increasingly difficult to get prescribers to return calls at all, let alone in a timely manner to prepare compounds. • It would also be helpful if the Board could articulate whether there will be a "phase in" period to allow pharmacists to make any adjustments to their practices in line with the revised Guidelines. • Comment on 5.4: This should read Pharmacists who compound medicines (for humans or animals) - the order should be changed, since our exemption for compounding is drawn from TGA exemptions rather than APVMA.

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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, this is a reasonable approach. There is no need to have a separate document when CPD requirements are discussed elsewhere.
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?**	It would be helpful for the Board to host a series of live webinars, which are also recorded and accessible for viewing at a later date, and also to include an FAQ document based on questions which they have received. It would be helpful for the FAQs to be updated as new questions are received.