Guidelines on compounding of medicines review - submission

The Pharmacy Board of Australia is inviting feedback on the clarity of the Board's consultation material, which includes its reasons for revising the guidelines, explanatory material about compounding and questions for stakeholders to consider during the public consultation phase that will follow this preliminary consultation phase. All questions are optional, and you are welcome to respond to any that you find relevant or have a view on.

Please note that submissions received during the preliminary consultation phase will not be published on the Board's website. However, you can request that your submission be published after the public consultation process.

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, I want my responses to be published after public consultation

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

Name: [redacted]

Organisation: **The Pharmacy Guild of Australia**

Contact email: [redacted]

1. Has the Board sufficiently highlighted the proposed changes to its guidelines and the reasons for proposing the changes?
The Guild feels the text under "Options – guidelines" (page 14 of 15) is not necessary. The public are not being asked to vote on a resolution. Consider rephrasing as "The Guidelines are being reviewed and updated because…"
2. Does the table of changes provide sufficient information? If no, do you have any suggestions for improvement?
In general, yes. One reviewer stated, "*mapping of changes is also valuable*." However, another reviewer commented: *"No. To understand the changes for each section I had to pull up the old Guidelines and read them section by section. The table is a good "summary" but not detailed enough to fully understand the changes. I personally, was more interested in the new content which could perhaps be displayed in a different colour."*

3. Are the consultation questions in the table clear? Should there be additional questions asked?

We suggest:

Q.6 should be phrased: "Please provide any other feedback about the guidelines".

Q.7 should have additional text, "why or why not?" added to question.

The public consultation paper includes case studies to demonstrate the intended application of the guidance in pharmacists' practice.

4. Are the case studies clear and helpful? Are there additional issues to be highlighted or other case studies that would be helpful?

General comments

Suggest making the case studies clearer by adding the word "Comment" or similar to each case study after the facts of the case are presented.

For example, in Case Study 1 (p11 of Public Consultation), the first 4 paragraphs detail the case. Then the word "Comment" should appear prior to the final (5th) paragraph. I.e.

> ...
>
> The pharmacist notifies the patient and the prescriber that the medicine should not be compounded and discusses the alternative suitable medicines that are entered on the ARTG, are available and may address the patient's needs.
>
> **Comment:** The revised guidelines now state that if an appropriate combination of commercial medicines is available, a pharmacist must not compound the medicine (including if the medicine can be compounded at a lower price than the available commercial medicine) or compound a slightly different medicine where it is unlikely to produce a different therapeutic outcome. Medicines that are entered on the ARTG have been evaluated for quality, safety and, where appropriate, efficacy and/or performance. This case study highlights that there are several important considerations to inform how to respond to a request for a compounded medicine.

Similar for other case studies.

Case study 2- Batch compounding – Recommend that the case provides clearer justifications/more examples about batch preparations when it comes to supply order through a phone call without the presentation of a script in the pharmacy premises.

Case study 2- Batch compounding - The details explained in the Case Study may contradict what the guidelines actually state. I.e.

> (In case study)
> "As the pharmacist does not have a prescription for each named patient, they are not permitted to compound a batch in anticipation of receiving a prescription."
>
> (In Guidelines Section 5 - Batch Production, p.13 of 21)
> the Guidelines state that pharmacists can produce a batch for individually named patients if "*a prescriber regularly prescribes a medicine that must be compounded and the pharmacist has received multiple prescriptions for that medicine.*"
> The Guideline does not make mention of requiring a script prior, only individually named patients.

Comments from reviewer:
I feel the important point to make in this situation is that a batch production is allowed but the end-product being produced must be for a specific patient, for a specific therapeutic application to meet TGA exemption rules.

It is very common for patients to receive repeat prescriptions and in relation to the **Statement of Assessment Question 3D** "Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved" I think it's unrealistic and not reasonable to impose extra labour costs on the labs to discourage batch production when the TGA rules of the end-product distribution are being followed.

The Guild believes this case needs to be revised for clarity as it may be misinterpreted.

Case study 2 – The batch compounding example introduces a challenge that pharmacists practising in rural areas face in providing medicines to consumers in a timely manner. While the case and commentary clarify the Board's position, the FAQ does not address the issues experienced by rural pharmacists and consumers. Discussing the options available to assist health outcomes in rural and remote Australia would be valuable within the case.

Case Study 6 – Confidential Formula

Comment from reviewer:
"I understand the reasoning behind this case study, but I don't feel the Guidelines match the Case Study.

The Guidance in Section 11 of the Guidelines state that the label must contain:

- the name and strength of each active ingredient (especially if a formula other than a standard pharmacopoeial formula is used),
- the name and strength of any added preservatives,
- the name of the formula as described in a standard pharmacopoeial reference book (where applicable), and
- the dose form and quantity supplied.

It does not state that the base is required on the label.

Bases used between labs are likely to vary if the doctor has not specified a base, therefore making the formulations slightly different every time.

These changes are not intentional, but they definitely occur depending on lab processes and suppliers.

I feel this case study needs to focus more on providing a "detailed" formulation sheet if requested, that includes the base used and method of production. This case study does not breach the guidelines if they have incorporated all of the labelling requirements above and only excluded the base."

Case study 7 - Risk assessment – should include a flowchart for risk assessment undertaken by the pharmacist for clearer justification.

The Board would like consumers to provide feedback to this consultation and has developed a consumer fact sheet on compounding of medicines by pharmacists.

5. **Do you think the consumer fact sheet will:**
   a. **help consumers understand how compounded medicines are different to other medicines, and**
   b. **support consumers to participate in the consultation?**

5a:

Comments from reviewer:
"Yes, but it's quite long. Could be condensed, some sections can be integrated. A simplified consumer fact sheet may be more effective."

The desire to keep language as simple as possible is recognised, but it may be more factual to state "prepares a medicine" rather than "makes a medicine".
"*Makes*" a medicine infers aspects such as synthesis, extraction, purification etc. which are not part of the compounding process.
Whereas the verb "*prepare*" aligns more with compounding a patient-specific dose form.

Suggest (at top of p.2) addition as follows: "If compounding the medicine requires special skills, education and training, which the pharmacist hasn't completed or requires equipment that is not available at the pharmacy, you may be referred to another pharmacy."

In following paragraph "Can I choose where to get my medicine compounded?" change phrase "not all pharmacists" to "not all pharmacies".

5b:

Comments from reviewer:
"No. I don't believe patients understand the process enough to provide assistance in the consultation process."

Comments from reviewer:
"As a part of the consultation process, consumer focused resources should be assessed and commented by relevant consumer groups". The consumer fact sheet should also be reviewed by representatives of culturally and linguistically diverse populations, as well as any other populations with known lower rates of health literacy.

6. Are the language and structure of the revised guidelines helpful, clear and relevant? Why or why not?

Structure of revised document is an improvement on previous version.

Language is generally clear and relevant. Further comments and suggestions to improve the revised guidelines have been provided in response to Q.7.

7. Do you have any other feedback about the guidelines or public consultation material?

Public consultation paper. Top of p.9. "Policy Direction 2019-02"
It is unclear which policy direction this refers to. Does 2019-02 refer to a date or a document number?

Cross profession consultation and communication

Will the consultation be advertised to prescribers (medical practitioners), particularly those who commonly prescribe medicines that require compounding? Suggest the Pharmacy Board also advertises the public consultation to key professional bodies, in particular: Australian College of Dermatologists, Australian Paediatric Society, and Royal Australian College of Physicians.

Once changes to Guidelines are approved the Board's expectations should be communicated to prescribers too. We recommend that the Pharmacy Board works with the Medical Board to prepare a factsheet for prescribers. It is important that prescribers are not ordering medicines in conflict with Board recommendations. Doing so places pharmacists in an invidious position.

The Guidelines are silent on the compounding of products that might be considered a placebo. Does the Board have an opinion on whether pharmacists should be entitled to compound, or to refuse to compound, a medicine which is prescribed chiefly for its placebo effect.

We recommend that the Guidelines clarify that a compounding pharmacy cannot prepare on behalf of another pharmacy unless it holds a manufacturing licence. This situation could be another case study.

Guidance 1.1.1 (p.6 of 21) The availability of a commercial medicine.
The phrase "cannot be accessed within the timeframe" doesn't clarify a number of situations that can be associated with the unavailability of a medicine, and could be misinterpreted.

Guidance 1.1.6 (p.7 of 21) Patient consents to receiving a compounded medicine.
It is unclear what circumstances might comprise an emergency?
Suggest that example(s) is provided in the form of a case study.

Definitions:

- Suggest that the list of definitions be sorted alphabetically.
- If sub-definitions are required (e.g. simple, complex compounding) these could be indented.
- Suggest that “A co-regulatory jurisdiction” does not require the indefinite article “a” at start.
- Consider whether the term “supervising pharmacist” requires definition.

Section 3: Facilities, working environments, equipment and support staff

The Guild recommends inclusion of the following clause:

All practice settings performing complex compounding should be accredited with a recognised quality assurance program:

- For community pharmacies, the Quality Care Pharmacy Program, or other equivalent program providing assurance to AS:85000.
- For hospital pharmacy departments, the National Safety and Quality Health Service (NSQHS) Standards.

Section 4: Formulation considerations
We note that Section 4 contains the following text:

> Pharmacists may be required to manipulate a commercial medicine to make it ‘ready to administer’. If this is in accordance with the manufacturer’s instructions, for the purposes of these guidelines this is not considered compounding. Examples of this may include reconstituting oral antibiotic mixtures and aseptic transfer in accordance with the manufacturer’s instructions.

We suggest that this clarification would be better placed in a different section. Perhaps the Introduction, or Section 1, as well as the Definitions.

We also recommend the statement be expanded to specify whether preparation of sterile admixtures, preparation of products such as TPN, chemotherapy are considered compounding, for the purpose of the Guidelines.

Section 4. Formulation considerations

A reviewer provided the following comment:

> “I feel there should be a strong mention of Beyond Use Date (BUD’s) Studies in this section which has been heavily promoted by both PCCA and Medisca after the APF updates.”