



Guidelines on compounding of medicines review - submission template

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Please note that submissions received during the preliminary consultation phase will not be published on the Board's website.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: _Office of the Chief Pharmacist, Department of Health and Wellbeing SA Health

Contact email: [REDACTED]

1. Has the Board sufficiently highlighted the proposed changes to its guidelines and the reasons for proposing the changes?
Yes, only suggestion is to clearly define early in the document that the guideline is applicable to all practice settings (i.e. community, private hospital, public hospital, etc).
2. Does the table of changes provide sufficient information? If no, do you have any suggestions for improvement?
Yes.
3. Are the consultation questions in the table clear? Should there be additional questions asked?
Nil comment.
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?

Case studies are useful but for Case studies 4 and 7 suggest consideration of:

- Case study 4 – initial supply is reasonable, but arrangements should be made for subsequent/ongoing supply via other arrangements (i.e. SAS)
- Case study 7 – strongly suggest PBA consider a document be developed as a *risk assessment template* that all practitioners can refer to. This will ensure national consistency across the profession and more importantly avoid inadvertent patient harm.

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.

Nil comment.

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

Yes.

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

- The document would be well supported by the inclusion of a template (*batch sheet*) for use by the profession for manufacturing of products. This would ensure consistency of practice and clear documentation of compounded products for the patients records (and sharing with health professionals as required).
- 1.1.2 (pg. 7 of 21) makes reference to 'Competence to compound medicines' but with very minimal explanation or guidance as to what the PBA deems as 'competent'. This section requires further consideration.
- Nil mention of PPE requirements for compounding of medicines, both for staff safety and product quality. While there is a general reference (3.1) to facilities and equipment, staff and patient safety should be addressed by appropriate PPE requirements.
- Clearly define in the document 'reconstitution' versus 'compounding' as this should not be assumed.
- Section 3 (3.1 specifically) is silent on appropriate 'benchtop' facilities versus 'clean room' or a 'compounding laboratory'. Suggest some supplementary text on this topic to be clear and not leave this open to interpretation.