

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Please note that submissions received during the preliminary consultation phase will not be published on the Board's website.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

Please do not publish the name or contact details of NT Health employees

Name: [REDACTED]

Organisation: NT Health

Contact email: [REDACTED]

1. Has the Board sufficiently highlighted the proposed changes to its guidelines and the reasons for proposing the changes?

Pages 4 to 15

Consider re-arranging the overview section to have the paragraphs grouped by timeline, i.e. moving the final paragraph relating to 2015 to become paragraph 3.

Consider adding Option 3 – Retire compounding guideline to page 14. The justification of compounding being high risk and a gap between the Therapeutic Goods Legislation and guidance for practitioners to practice safely under this act is still required. There may be questions throughout the consultation process to clarify the need for PharmBA guidelines with the update and additions provided within the APF25. NT Health is supportive of this guideline remaining and consider the alignment with the updated APF, and removal of duplication helpful.

Please make the title "Australian Pharmaceutical Formulary Handbook (APF25)" consistent throughout the guideline and consider referring to it as its abbreviation after first use, APF, as it switches to include Australian Pharmaceutical Formulary *and* Handbook.

Overall, the Board has sufficiently highlighted the proposed changes, including background & rationale, for the proposed changes. The Case Studies are a welcome addition for clarity and have captured key examples which occur in practice.

2. Does the table of changes provide sufficient information? If no, do you have any suggestions for improvement?

Page 38 to 41

Table of Changes provides sufficient summary of information on the changes between the current Guidelines and the draft revised Guidelines; subtitle comparison of the respective Guidelines allows for easier comparison with comments/notes of changes provided for the draft revised guidelines.

For ease of reviewing, having the table of comparison as a standalone document, or consider including hyperlinks of the headings for the draft revised column (right hand side) to allow quick reference to the relevant sections. Additionally, hyperlinks in the draft guideline content list to help with navigation.

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

Page 14

Consultation questions are clear & specifically request comment on the three main changes in the revised Guidelines (addition of medication supply pathways, highlighting when guidance on animal patients is different to human patients, and retirement of professional practise profile for complex compounding).

Question 3 is potentially not adding value as it currently stands. Any content changes can be reflected by consultation responses received in question 4. Please consider changing question 3 to ask for comment on the order of the content (or flow) of the guideline.

Question 5 (of this preliminary consultation questions) could be then reframed to seek feedback on the consumer fact sheet as part of the consultation. This may be a missed opportunity for refining the fact sheet as well as an additional opportunity for consumers to provide feedback either via organisations or independently at different stages of the review. Some consumers may benefit from seeing the guideline and the fact sheet together to provide feedback.

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?

The case studies are clear and helpful in assisting understanding the practical applications of the revised guidelines; they are welcome addition.

As batch compounding is a query and concern that is often raised from the hospital sector, it may be helpful to revise case study 2 to position it from a non-TGA hospital facility.

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?**

Page 42 to 44

Consumer fact sheet is welcome and may help consumers to understand the differences in compounded compared to non-compounded medicines. This area is complex for consumers and health professionals, particularly those who do not compound, and would be a welcome resource for compounding pharmacies to provide consumers.

Providing multiple opportunities for consumers to participate in the public consultation process for the revised Guidelines is supported. Per Response to Question 3, asking this question as part of the consultation questions, may help to support consumer participation as a question

aimed primarily to gather their vital feedback. An additional independent consultation without the guideline (i.e. standalone fact sheet) would be recommended.

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

The language and structure of the revised guidelines are helpful, clear and relevant. Separating context from Board Guidance and other format changes do provide a significant improvement in clarity to the revised Guidelines (compared to current format).

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

NT Health look forward to providing specific content feedback on the Guidelines during the public consultation process.