

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Please note that submissions received during the preliminary consultation phase will not be published on the Board's website.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

Name: [REDACTED]

Organisation: Society of Hospital Pharmacists of Australia (SHPA)

Contact email: [REDACTED]

<p>1. Has the Board sufficiently highlighted the proposed changes to its guidelines and the reasons for proposing the changes?</p>
<p>Yes. The proposed changes are clear. The structure and content are similar to the previous version of the guideline.</p>
<p>2. Does the table of changes provide sufficient information? If no, do you have any suggestions for improvement?</p>
<p>Yes, the table provides sufficient information.</p>
<p>3. Are the consultation questions in the table clear? Should there be additional questions asked?</p>
<p>The proposed consultation questions are clear. Question 7 is particularly relevant, given that members feel that the Professional practice profile for pharmacists undertaking complex compounding is not utilised widely by pharmacists.</p> <p>SHPA welcomes the addition of the of SAS pathway in the medicine supply pathways section and therefore believes that this question is appropriate.</p>

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?

SHPA believes that the case studies are sufficient overall and demonstrate the content of guidelines in pharmacy practice clearly. However, members note that the majority of case studies present community pharmacy focused issues as opposed to hospital pharmacy issues.

A further hospital pharmacy based case study is suggested, for example a case study concerning compounding of a product which has been contracted to a TGA facility for manufacture without the product requiring entry on the Australian Register of Therapeutic Goods (ARTG).

If finalised by time of the new Guidelines have been developed, a hospital focused case study could also refer to the TGA's Emergency Medicine proposed reforms and upcoming amended regulations to allow extemporaneous compounding without a named patient in an emergency.

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?

Yes, a consumer fact sheet would be useful to provide to patients when a medicine is required to be compounded. It can assist in explaining to patients the reasons for and safety aspect of compounding and therefore the implications on pricing of their compounded medicine.

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

Yes. Plain and concise language has been utilised.

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

No.