

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Please note that submissions received during the preliminary consultation phase will not be published on the Board's website.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

Organisation: Office of the Health Ombudsman

Contact email: [REDACTED]

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

The OHO is of the opinion that the Pharmacy Board has sufficiently highlighted the proposed changes to its guidelines and the reasons for proposing the changes.

The OHO supports the clarification concerning:

- provision of compounded products when a commercial preparation may be available, including clarification of a commercial preparation to include SAS products (when available)
- risk assessment required to be undertaken prior to compounding (including repeat compounding)
- differentiation between veterinary and human use,
- compounding of batch products,
- information to be given to the patient, and
- the use of "proprietary" formulations

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

The OHO is of the opinion that the table provides sufficient information to the reader to enable them to identify the proposed changes to the compounding guidelines.

<p>3. Are the consultation questions in the table clear? Should there be additional questions asked?</p>
<p>The OHO believes that the consultation questions in the table are clear and concise and will be able to obtain the required feedback on the proposed changes to the compounding guidelines.</p>
<p>The public consultation paper includes case studies to demonstrate the intended application of the guidance in pharmacists' practice.</p>
<p>4. Are the case studies clear and helpful? Are there additional issues to be highlighted or other case studies that would be helpful?</p>
<p>The OHO believes that the case studies are clear and helpful. Further formatting of the case studies may assist the general public identify as to where each case study starts and ends.</p>
<p>The Board would like consumers to provide feedback to this consultation and has developed a consumer fact sheet on compounding of medicines by pharmacists.</p>
<p>5. Do you think the consumer fact sheet will:</p> <ul style="list-style-type: none"> a. help consumers understand how compounded medicines are different to other medicines, and b. support consumers to participate in the consultation?
<p>The OHO believes that the compounding fact sheet is clear and will help consumers understand the difference between regular medications and compounded medications. The fact sheet will assist consumers to understand the pharmaceutical regulation process and where compounding fits within this process and support their participation in the consultative process.</p>
<p>6. Are the language and structure of the revised guidelines helpful, clear and relevant? Why or why not?</p>
<p>The OHO believes that the language and structure of the revised guidelines are helpful, clear and relevant.</p> <p>The OHO supports the realignment of the guidelines structure to better reflect the important considerations prior to compounding a medication.</p>
<p>7. Do you have any other feedback about the guidelines or public consultation material?</p>
<p>The OHO supports the proposed changes to the compounding guidelines and associated supporting material and has no further feedback about the guidelines and public consultation material</p>