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Please note that submissions received during the preliminary consultation phase will not be published on the Board's website.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

Organisation: Australian Commission on Safety and Quality in Health Care

Contact email: medsafety@safetyandquality.gov.au

1. Has the Board sufficiently highlighted the proposed changes to its guidelines and the reasons for proposing the changes?
Yes
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?
The Commission recommends clarification about different practice settings in which pharmacists may be exempt from parts of these guidelines. An additional consultation question about the applicability of the guideline to pharmacists across various settings may help inform this recommendation. Also refer to comments at question 7c.
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 were very clear. Pharmacists often have questions seeking clarification on the use of guidelines in practice. These case studies will certainly assist pharmacists in applying the guidelines using real examples and scenarios.

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?

The consumer fact sheet is a useful document to consumers who would like to understand how compounded medicines differ from commercially available medicines. Engagement with a health literacy organisation and/or consumer group could ensure the content is consumer-friendly and uses plain language. Where possible translations into different languages would also be useful. Further information could be provided around the safety of buying compounded medicines online either in this fact sheet or a supporting document. It may be useful to add a glossary for terminology within the fact sheet to encourage consumer confidence and support participation.

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?

a. The Commission recommends strengthening the guidelines in relation to where complex compounding can be conducted. This is a key source of safety and quality risk relating to compounding. Recommended wording for *Guideline 3 Facilities, working environments, equipment and support staff* (page 9 of 21):

   Existing paragraph
   As required under relevant state and territory legislation, premises must be accredited and/or approved and/or registered by the relevant jurisdictional authority and operate in accordance with any legislation or guidelines published by those authorities.
   Recommended addition to the above paragraph
   All complex compounding should be conducted in pharmacy premises that are independently accredited to appropriate safety and quality standards developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC), or other profession-specific or industry-specific standards.

b. The National Safety and Quality Primary and Community Healthcare Standards (the Standards) have been developed for primary and community healthcare services, and aim to protect patients from harm and improve the quality of health care delivered. The Standards include Clinical Governance, Partnering with Consumers, and Clinical Safety. Healthcare services implementing the Clinical Governance Standard together with the Partnering with Consumers Standard will establish a clinical governance framework. This will provide a foundation to support the implementation of the Clinical Safety Standard, which considers high-risk areas commonly encountered in primary and community healthcare services. The Commission is currently working with the Pharmacy Guild of Australia to support alignment of the AS85000:2017 Quality Care Community Pharmacy Standard to the Commission's Standards.

   The National Safety and Quality Health Service Standards aim to protect patients from harm and improve the quality of health care delivered in a hospital setting. They provide a quality assurance mechanism that tests whether relevant systems are in place to ensure that expected standards of safety and quality are met. State and territory regulators require all hospitals to be independently accredited to the NSQHS Standards.

   The NSQHS Standards and the National Safety and Quality Primary and Community Healthcare Standards are aligned in structure and intent and should be referenced in the guidelines under the subheading, *Quality Standards* (page 3 of 21).

c. The Commission recommends further clarity is provided regarding the degree to which these draft Guidelines apply to pharmacists in different practice settings, such as private and public hospitals, where there may be complex governance structures under state and territory licensing requirements and policy directives. These may facilitate compounding outside the parameters specified in the draft Guidelines. The Guidelines should clearly state to what extent they also apply to a registered pharmacist employed by a TGA licensed manufacturer, which also performs compounding of medicines.

   An example of where lack of clarification about scope and practice setting may cause confusion in the draft guidelines (page 2 of 21): '*In addition to providing guidance for pharmacists compounding a medicine, these guidelines also set out the obligations of pharmacists responsible for the operation of the pharmacy premises where the compounding occurs, e.g. the proprietor of a community pharmacy or the director of a hospital pharmacy department*.'

   The guidelines also state that (page 13 of 21): *'As set out in therapeutic goods legislation, a batch cannot be prepared in anticipation of receiving orders and/or prescriptions'.* However, some public hospital pharmacy departments routinely batch prepare commonly compounded medicines in anticipation of an order. The guidelines should be more explicit about when and where exemptions may apply. As these guidelines are intended for all pharmacists, we believe it may be useful to add a further comment about the scope of the guidelines under the subheading, *Who needs to use these guidelines*, with reference to other state and territory legislation and policy directives that may apply.

d. The Commission recommends defining and making clear the distinction between sterile and aseptic procedures. Correct terminology used throughout the guideline will improve useability in conjunction with other standards and guidelines. Where compounding of a medicine is not a sterile procedure, the word 'aseptic' should be used instead. Consider adding a reference to the Australian Guidelines for the Prevention and Control of Infection in Health Care.

e. The Commission recommends reference to infection prevention and control practices in various parts of the guidelines. The Australian Guidelines for the Prevention and Control of Infection in Healthcare and Principles for aseptic technique: Information for healthcare workers could be referenced throughout the Guideline. This will improve familiarity with, and adherence to infection prevention and control requirements, and associated risks, during the compounding process.

f. In relation to *Guidance 5 Batch Preparation*, consider the risks associated with pharmaceutical waste production during this process. This supports sustainability actions of the National Safety and Quality Health Service Standards.

g. In reference to *Guidance 7 Managing risks that may lead to injury,* we suggest making additions to highlight the safe handling of sharps and the reporting processes for occupational risk and injury. Consider referring to the Hierarchy of Controls, which is the model recommended by Safe Work Australia for work health and safety risk management. The Commission has prepared information and resources on use of the Hierarchy of Controls for infection prevention and control.

h. The Commission recommends including reference to the National standard for labelling dispensed medicines under *Guideline 11 Packaging and Labelling Requirements*.

i. The Commission recommends including reference to the Australian Charter of Healthcare rights under *Guideline 14 Supporting Informed Patient Choice*. The charter provides information on patient choice, and partnership in care.

j. Consider adding hyperlinks to resources, where available, to improve accessibility.