University of
South Australia

30th June 2014

Dear Sir/Madam,

Re: Feedback to the draft guidelines on compounding of medicines

Please see our feedback to the draft guidelines on compounding of medicines dated 28th of April 2014.

1. Do the draft guidelines clearly differentiate between simple compounding and complex compounding?
   Yes it does.

2. Do the draft guidelines clearly outline which requirements apply to pharmacists who undertake either or both types of compounding (simple and/or complex compounding), and which requirements apply only to pharmacists who undertake complex compounding?
   The additional requirements for training/education, processes, premises and accreditation that should be expected of a pharmacist who undertakes (or pharmacy where) complex compounding should be specified in this guideline. This accreditation would also need to be addressed in the relevant Federal legislation.

3. Is the content of the draft guidelines helpful?
   Yes the content is useful. These reviewed guidelines once published should be reviewed periodically to address and provide guidance to contemporary issues and challenges faced by the profession.

4. Is there any content that needs to be changed, added or deleted in the draft guidelines?
   a. Title of the guidelines should be "compounding of medicinal products" rather than "compounding of medicines" to better reflect the compounding of medicinal products rather than medicines, per say.
   b. Page 6: Under subheading Therapeutic goods legislation:
      It would be extremely beneficial to pharmacists if the guidelines were to include links to the relevant (state and federal) legislation, for example the Health Practitioner National Law (South Australia) Act 2010 and those Acts relevant for each State or Territory. The guidelines should also ideally address the responsibilities/requirements of pharmacists involved in extemporaneously compounding schedule 8 drugs.
   c. Page 12: under subheading: Formulations for which precedents do not exists
      This section appears quite contradictory where this section starts off by

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saying that pharmacists could prepare a formulation based on "sound judgement based on current clinical and pharmaceutical knowledge and risk assessment" but then finishes off 'in the absence of such evidence (which is clearly lacking for this class of formulations as per title), pharmacists must not compound such products'. It makes the reader wonder whether the Board encourages the compounding of formulations for which precedents do not exist. A clearer stand on this issue should be made by the Board. This section also does not take into account drugs which have been compounded for novel/alternative use. For example, there is some evidence for the topical use of doxepin as an antipruritic.

d. Page 12: under subheading: Compounding of parenteral medicines in advance
   It would be clearer to the reader if the phrase "….. with a shelf life of less than 24 hours ……" was use to indicate the time frame rather than "…….. with a shelf life of up to 24 hours…….".
e. Page 13: "…. the Board discourages batch preparation."
   This is a very generalised and over simplistic view of batch preparation. This statement does not account for batch production of simple products with known stability data having a large turn over. This is where the guideline needs to be specific about not recommending batch production of medicinal products that require complex compounding where the dangers of making an error are higher which could potentially affect a greater number of individuals as compared to individualised compounding.
f. Page 13: "…… pharmacist's responsibility to counsel the patient and ensure……" this should read as " .. it remains the pharmacist's responsibility….." This has always been the responsibility of a pharmacist and not something new to dispensing compounded medicinal products.
g. Page 14: under subheading: Raw materials
   "not approved for human use" should be followed by 'but being used for humans' to be clear.
h. Page 15: under subheading: Counselling
   "…. ensure that every patient or their agent *are* offered……." this should read "…. ensure that every patient or their agent *is* offered……."
i. Lloyd Allen's name in the reference should have two 'l's. Best to list the reference texts in alphabetical order.

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5. Do you have any suggestions for questions to be answered in FAQ developed by the Board to support the guidelines?
   The FAQ section should develop with questions presented to the Board once the guidelines have been published.

6. Is the purpose of the practice profile clearly explained in the draft guidelines?
   The practice profile is not clearly explained in the draft. There are guiding principles to the development of the practice profile and as such does not appear to be fully developed at this stage.

7. Do you have any other comments on the draft guidelines?
   As stated above.

Yours sincerely,
The Pharmacy teaching group
University of South Australia