Public consultation on the draft *Guidelines on compounding of medicines*

28 April 2014

Responses to consultation questions

Please provide your feedback as a Word document (or equivalent)[1] to pharmacyconsultation@ahpra.gov.au by close of business on Monday 30 June 2014.

Stakeholder Details

If you wish to include background information about your organisation please provide this as a separate word document (not PDF).

Organisation name
Pharmaceutical Society of Australia (Chief Executive Officer: Dr Lance Emerson)
Contact information *(please include contact person's name and email address)*
Kay Sorimachi [redacted]

Your responses to consultation questions on the draft *Guidelines on compounding of medicines*

1. Do the draft guidelines clearly differentiate between simple compounding and complex compounding?
Since pharmacists are being introduced to the terms 'simple compounding' and 'complex compounding' for the first time (in a formal sense through the Board's guidelines), it would be useful to present their definitions earlier in the document (as opposed to including them solely in the 'Definitions' section at the back of the document). A suitable location might be on p. 10 under the scope statement in boldface. The definition of 'complex compounding' includes "micro-dose single unit dosage forms" as an example preparation. PSA believes it would be useful to include a definition for "micro-dose single unit dosage forms" in the Board's guidelines.

[1] You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you do supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx.

Several concerns have been raised in relation to the inclusion of all sterile work as 'complex compounding'. The current definition appears to include, for example, withdrawing a dose from an ampoule into a syringe, and transferring from an ampoule into an infusion bag. Clarification around this is requested as PSA has received queries in relation to pharmacists needing to meet requirements on complex compounding while these cited example activities are carried out within hospital wards by other health professionals.

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?

PSA strongly suggests it would be useful to provide a comparative table in the guidelines to articulate this information clearly.

3. Is the content of the draft guidelines helpful?

PSA believes there is scope for enhancing the usefulness of the guidelines. Pharmacists have suggested that information (in the guidelines or the FAQs) on ways to enhance understanding on what a compounded product means to the consumer would be useful.

Additional references might be useful on where consumers can access safety information relating to compounded medicines e.g. in the event of a spill at home.

Further specific suggestions are provided below in response to question 4.

4. Is there any content that needs to be changed, added or deleted in the draft guidelines?

Information on compounding of veterinary products

PSA acknowledges that compounding of veterinary products would be undertaken by a small proportion of pharmacists. The draft guidelines clearly outline the obligations of these practitioners as well as any pharmacist planning to compound any products for animal treatment to have undertaken appropriate education and sufficient training to demonstrate competence. However, generally speaking, we believe the information provided on veterinary compounding needs to be enhanced as follows.

- Information provided currently does not seem to be well structured and is difficult to locate. There is no consolidated section as information appears in various parts of the document; some information is presented under a dedicated heading (p. 11) and others appear somewhat ad hoc (e.g. on p. 10).

  In addition, the relevance of information in terms of where it is placed could be improved. For example, the paragraph on p. 11 under the subheading 'Veterinary products' refers to compounding of both simple and complex products and therefore the placement of this text under the broader sectional heading "competence to undertake complex compounding" is not ideal.

- In addition to consolidating the information, we believe key points warrant being drawn to the attention of pharmacists (note that some of these points will also be covered in the next edition (edition 23) of the *Australian pharmaceutical handbook and formulary* (APF), scheduled for publication in February 2015). For example:

  - requirement for the pharmacist to have received instructions to compound a product from a veterinary practitioner;

  - the ability for pharmacists to compound non-prescription ingredients for individual human patients without an instruction from a prescriber does not apply to products for animal treatment. Although this point is included in the proposed information sheet, we believe it is key information which should be presented in the guidelines;

- a reminder to consider any relevant requirements under state and territory legislation (e.g. labelling requirements specific to veterinary products).

- PSA also seeks inclusion of additional guidance points under '14. Advertising' (p. 15) on advertising by pharmacists relating to compounding of veterinary products where the advertisements are directed to the public or to veterinary practitioners.

Liability associated with veterinary compounding

PSA is aware that the Australian Veterinary Association (AVA) issues guidelines to its members on the preparation and use of compounded pharmaceuticals (accessed at www.ava.com.au/newsarticle/guidelines-prescribing-and-using-compounded-medicines). The document appears to have been developed in consultation with the Board.

In providing advice on the appropriate use of compounded veterinary medicines the AVA guidelines state (in part):

> *Liability for side effects, lack of efficacy or residues in food producing animals may remain with the prescribing veterinarian and/or the compounding pharmacist…*

PSA requests the Board to provide guidance (whether in the Board's final guidelines or not) on this matter.

The AVA guidelines also advise its members before engaging a compounding pharmacist to check the suitability of the pharmacist's experience and training in complex compounding of veterinary products, and whether they have access to appropriate references and texts for animal dosages and side effects. We therefore feel that the Board needs to provide guidance to pharmacists on these aspects.

Batch preparation

PSA is aware that circumstances and parameters around batch preparation and how best to limit potential risks have been considered by stakeholders over a considerable period of time. PSA recognises the importance of risk assessment and management in relation to all compounding activities but batch preparation in particular given the potential to impact negatively on a larger number of patients in the event of an error or contamination as highlighted in the draft guidelines.

We note the statement in the draft guidelines (p. 13) that the Board "discourages" batch preparation but does not explicitly preclude or prohibit the activity. Pharmacists have requested clearer advice in relation to what the implications might be for pharmacists if there is a disciplinary issue.

Further in relation to batch preparation, some pharmacists have suggested the following issues could be included or enhanced in the guidelines:

- Additional detail around quality assurance and quality control requirements of batch products.

- Possibly expand on the explanation, for example, that batch preparation is not recommended unless retention samples, quality assurance and assays are undertaken for batches.

- Greater attention to licensing or accrediting facilities involved in batch/complex manufacturing.

Other suggestions for minor amendment

- p. 9, third solid bullet point, and p. 13, second paragraph under the heading 'Risk assessment process for compounded products' – these refer to a specific section and table in edition 22 of the APF. Although the section and table will also be included in the next

edition of APF, this may change in the future. Therefore the label used for the reference, "the current edition of APF" may have an impact on the currency of the guidelines given a longer review cycle is proposed.

- Where the APF is referenced without edition details, please include the words "the current edition of" (or similar) – for example: p. 9, second paragraph; p. 16, section on reference texts; p. 16, definition for "simple compounding".

- It has been suggested that the *Australian code of good manufacturing practice for medicinal products* (available from the Therapeutic Goods Administration web site and referred to in the Background section (p. 6)) would be a useful addition to the list of reference texts (p. 16).

5. Do you have any suggestions for questions to be answered in Frequently Asked Questions developed by the Board to support the guidelines?

- **Compounding of veterinary products.** PSA notes the draft guidelines' reference to the Board's plans to publish a separate information sheet on the regulatory environment alongside the published final version of the guidelines. Nevertheless, PSA believes it would be helpful to include a series of Q&As which will clearly articulate the key points for pharmacists who are contemplating or undertaking compounding of products for animal treatment.

- **Packaging, labelling and counselling.** PSA believes additional information would be useful on requirements around labelling and counselling which would assist consumers in their understanding of what a compounded medicine is and the implications of this. PSA is aware that this has been a subject of discussion by stakeholders.

6. Is the purpose of the practice profile clearly explained in the draft guidelines?

No comments

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

It would be useful to be made aware of how the Board's substantial work on compounding now fits in with the number of compounding reviews undertaken by the Therapeutic Goods Administration over the past ten years.

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