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
School of Pharmacy, Curtin University, Western Australia
Contact information *(please include contact person's name and email address)*
Jennifer Dolzadelli [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?
The definition of Simple compounding overlaps with that of Complex compounding. Reputable references, including the British Pharmacopoeia, include a much greater range of preparations than are included in the APF. The list of examples of complex compounded preparations includes some preparations which pharmacists should be capable of preparing without additional training, There is one specific inconsistency in the guidelines. In "Competence to undertake 'simple compounding'", simple compounding includes APF preparations (excluding sterile preparations), while "Competence to undertake 'complex compounding'" lists capsules as complex compounded preparations. The APF includes a formula for Boric Acid Vaginal Capsules which should therefore be considered simple compounding. The APF is using capsule filling by weight for its formulation, but also states that a capsule machine (which fills by volume) can be used. The board may wish to make a distinction between the filling of capsules by weight and volume, or

[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.

oral versus vaginal capsules, or simply not specify capsules at all. It is my belief that filling capsules by weight or volume can both be competently achieved by a pharmacist without specialised training. Filling capsules by weight is a simple compounding task that doesn't require any specialised equipment. Filling capsules by volume, despite requiring the acquisition of equipment that could be considered specialised, should be within the capabilities of any registered pharmacist. Pharmacy students at this university receive instruction and (limited) practice in capsule filling by both methods. Modified release capsules are certainly complex compounding and are listed separately with precautions relating to these being addressed in the section "Formulations for which precedents do not exist". Similarly, "micro" dose capsules and hormones are separately classified as complex compounding.

The preparation of troches/lozenges does not require skills that that lie outside the training of a pharmacist and is analogous to the preparation of suppositories. Suppositories are described in the APF, although no official APF formulations are listed. Preparation of suppositories is a traditional skill of the pharmacist and training in this is provided to pharmacy students at this university. The draft guidelines do not specify whether suppositories/pessaries are considered to be simple or complex compounded preparations. Troches, like suppositories, can be used for local or systemic administration of medication and the risks associated with the preparation and use of each are different. The preparation of systemically acting hormone-containing troches is already deemed complex because of the OHS hazards associated with these substances, and as there are currently no troches listed in the APF, troches as a dosage form need not be specified as complex.

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?

Yes

3. Is the content of the draft guidelines helpful?

The guidelines are generally helpful. The Background draws together the regulations and professional guidelines that relate to compounding.
Categorisation of simple and complex compounding in the guidelines is problematic. The APF defines Complex compounding as: *the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for immediate use by a specific patient and that requires or involves special competencies, equipment, processes or facilities. Examples are sterile preparations and preparations containing ingredients that pose an occupational health and safety hazard (such as cytotoxics or hormones), micro-dose single‑unit dosage forms, and sustained-release or other modified‑release preparations.* The skills that are considered "special competencies" and equipment that is considered "specialised" do not necessarily relate to the examples of complex compounded preparations listed in the draft guidelines.

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

I do not think that the guidelines should be too prescriptive in terms of the type of non-sterile preparations that are considered to require complex compounding. The requirement for quality of the final preparation, along with the definition in the APF should guide pharmacists to compound at their level of competence while allowing for any future additions to the APF formulary.

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

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

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

It is not clear that the "Guidelines" and the "The practice profile" are the same document. The statement, "the practice profile is referenced in the guidelines" suggests that it is a separate document that is available elsewhere, whereas it is actually embedded in the guidelines.

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