



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
PCCA Pty Ltd
Contact information (please include contact person's name and email address)
Frank Raue- General Manager [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?
There is a lack of clarity in the definition and legislation explanation- noted in section 4 of PCCA's response.
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?
Again, there is a lack of clarity in the definition and legislation explanation- noted in section 4 of PCCA's response.
3. Is the content of the draft guidelines helpful?

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.

Yes

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

Item 11, (page 4) –reconstitution of sterile products. The reconstitution of a commercial product according to the manufacturer's instruction is by definition not compounding-otherwise this would impose impractical requirements that are unnecessary. PCCA believes reference to reconstitution of sterile products should be deleted.

Page 6- 'Compounding Veterinary products'- The term 'instructions' is confusing and we believe this terminology would be better described as ' a Veterinarian must provide a valid prescription for compounded product for a specific named patient.'

Page 7 - 'Premises at which medicines may be compounded and supplied to patients' – PCCA believes the statement 'Similarly, pharmacists cannot prepare medicines extemporaneously at a pharmacy or private hospital for supply by wholesale unless their premises are a TGA licensed manufacturer' is misleading. This implies that a TGA manufacturing license permits a pharmacist to prepare and supply any therapeutic product by wholesale, however the product must be entered on the ARTG unless exempt which is limited to a specific product for a specific patient. The only therapeutic products that could be prepared by a TGA licensed pharmacy and supplied by wholesale must also be registered on the ARTG.

Page 10 'A commercial product may be considered unsuitable for a particular patient if an allergy to an excipient is the commercial product was experienced' – this statement implies that this is the only reason for the unsuitability of a commercial product. There are many others, such as unsuitable dose/concentration, dosage form-(example, difficulty in swallowing), medication vehicle, discontinued, unavailable (example out of stock) commercial product etc. This statement may be better worded as 'An example of.....' This section could be improved by outlining the typical reasons that a commercial product may be considered unsuitable for a particular patient.

Page 11 Definition of complex compounding – the definition is similar to, but not identical to the definition in the current APF. There is potential contradiction in defining micro-dose single unit dosage forms containing less than 25mg of active ingredient as 'complex' but then including all single unit dosage forms (tablets, capsules, troches) as 'complex'. Is a moulded tablet or capsule containing more than 25mg a 'complex' compounded product? We assume the concern is dose uniformity associated with micro-dose products rather than all single unit dosage forms. The APF definition seems more appropriate.

Page 12 Compounding of parenteral medicines in advance – this section is confusing since the Therapeutic Goods Regulations cited in the 'Background on the regulation of compounding by pharmacists' precludes the compounding of therapeutic products in advance of a prescription/order. If 'in advance' relates to the preparation of parenteral medicines that will not be used immediately, then why is there an 'increased likelihood of dose administration errors associated with the compounded product' that is not present when the product is used immediately. PCCA doesn't see why preparation 'in advance' increases this risk.

The statement that 'Only medicines for parenteral administration with a shelf life of up to 24 hours should be compounded by a pharmacist for use by a specific patient' is not supported by the APF which requires the pharmacist to support assigned expiry dates with literature or stability studies. This restriction is also contrary to USP Chapter 797 (to which the APF also refers) which requires for high risk products, in the absence of a sterility test, an expiry date of 24 hours at room temperature, 3 days refrigerated or 45 days at -10 °C or colder. Low and medium risk compounded products have more extended expiry dating. Limiting expiry dates for compounded parenteral products to 24 hours will significantly increase costs and accessibility for patients when it is not justified and contradicts the APF, USP and SHPA compounding guidelines.

Page 12 Manipulation of products in accordance with manufacturer's instructions – preparation of a medicine according to a manufacturer's instructions is not considered compounding. For example the reconstitution of an antibiotic suspension according to the manufacturer's instructions should not require the additional precautions in the guidelines even though the product could be considered a complex compounded product.

Page 13 Supervision of appropriately trained staff – Since compounding is an activity that must be directly supervised by the responsible pharmacist, it should be noted as one of the activities requiring direct supervision with a limitation of one pharmacist to two technicians in the Board's Guideline on Dispensary assistants/dispensary technicians and hospital pharmacy technicians.

Page 14 Additional requirements relating to facilities, working environments and equipment applicable to complex compounding – This section does not seem to add anything more than is written in the preceding paragraph. If the intention is to draw attention to particular risks associated with complex compounding that require special facilities, working environments and equipment considerations, then they should be specifically mentioned here. It would be useful to point out that sterile product must be prepared in clean room facilities meeting Australian standards, and that equipment must be dedicated for this purpose. In addition, pharmacists must ensure that processes, cleaning, and equipment have been validated as suitable for their purposes. Similarly cytotoxic chemicals must be prepared using dedicated facilities and equipment. The compounding of hazardous or irritant ingredients requires facilities and equipment that ensures that there is no significant risk of cross contamination of products or contamination of staff, public and the environment.

Page 14 Item 6 Potential for contamination due to injury – this section could also include a note on potential for injury due to contamination as may happen if adequate training, containment systems and safety apparel is not used. Reference should be made to the Workplace Safety section of the APF, pertaining to use of PPE & additional precautions – eg baseline and periodic pathology monitoring if ingredients present a risk of toxicity.

Page 14 Item 7 Raw materials – this section doesn't do anything other than to refer to the APF. Given the recent worldwide concerns with counterfeit drugs, the Board should emphasise the APF direction to use reputable suppliers of ingredients such as suppliers holding a TGA licence. Pharmacists should be discouraged from purchasing large quantities of ingredients directly from manufacturers in other countries unless they can be assured of the quality of the ingredients through evidence of TGA licensing or independent testing of each batch of ingredients.

Page 14 Documentation – Policies and procedures should also be in place to:

Document requirements for facilities and equipment

Ensure the facilities and equipment are cleaned and maintained

Ensure all staff are trained and appropriately qualified

Ensure products and ingredients are packaged, stored and handled so as to maintain safety and efficacy

Ensure patients are counselled on the use, storage and disposal of compounded products

Ensure ingredients are of suitable quality and are stored, handled and disposed of so as to protect personnel and the environment.

Page 16 Definition of complex compounding – the definition is similar to, but not identical to the definition in the current APF. There is potential contradiction in defining micro-dose single unit dosage forms containing less than 25mg of active ingredient as 'complex' but then including all single unit dosage forms (tablets, capsules, troches) as 'complex'. Is a moulded tablet or capsule containing more than 25mg a 'complex' compounded product? We assume the concern is dose uniformity associated with micro-dose products rather than all single unit dosage forms. The APF definition seems more appropriate.

Page 17 Definition of Unit of issue – We don't think the definition used here is accurate. A unit of issue is not necessarily 'a quantity of a unit dosage formulation to be supplied for the treatment of an individual patient' as this excludes liquids and semi-solid products. The words 'unit dosage' should be removed.

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

Questions about supply chain models would be helpful in providing clarification for compounding pharmacists and pharmacists who do not compound. For example 'Can a pharmacist preparing a compounded product supply that product to another pharmacy for dispensing to a patient?' and 'Can a pharmacist preparing a compounded product supply that product to a medical practitioner or veterinarian for supply to a patient?'

'Can a pharmacist supply a compounded product to a veterinarian on his/her order if it is not for a specific animal?'

'Can a non-prescription compounded product be offered for general sale (not for a specific patient) in the pharmacy?'

'Does holding a TGA manufacturing licence mean that a compounding pharmacy can prepare and supply any compounded product by wholesale ie not for a specific patient?'

'Does holding a TGA manufacturing licence mean that a compounding pharmacy can prepare and

supply compounded versions of commercially available products in any quantity?'
'Can a compounding pharmacist supply API's to other pharmacies by wholesale?'

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

Yes, however it may be difficult for pharmacists to identify areas requiring further training or education due to the size of the document and duplication from the practice profile for pharmacists in general.

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

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