Public consultation on the review of guidance on expiry of compounded parenteral medicines – Pharmacy Board of Australia *Guidelines compounding of medicines*

on

1 February 2016

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 Wednesday 30 March 2016.

Stakeholder Details

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

Organisation details PCCA TGA license supplier of pharmaceutical ingredients , education and training for compounding pharmacists
Organisation name: PCCA [redacted]
Contact name: Frank Raue GM PCCA / Marina Holt Education and Training Manager PCCA [redacted]
E-mail address: [redacted]

[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.

Your responses to consultation questions on the draft proposed guidance

1. Has the proposed guidance been expressed clearly?	Yes, for the most part, but there are still some unanswered questions/omissions (see questions 4 and 5 on this page) We feel that in a compounding pharmacy setting that adopting the USP 797, which already addresses sterile compounding would be appropriate.
2. Does the revised guidance adequately address the concerns raised by stakeholders, that the published (postponed) guidance would inhibit or impact patient access to compounded parenteral medicines?	Yes- these concerns have been addressed.
3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?	Yes
4. Do you have any suggestions for questions to be included in the Board's FAQ for pharmacists on the compounding of medicines, to support pharmacists in their understanding and application of this guidance?	Yes- (see also comments below, in questions 5) 1. If I am currently compounding sterile parenteral medicines, how long will I have to implement the proposed changes 2. The proposed document mentions self- assessment. Will a self- audit (assessment) template be made available by the Pharmacy Board, or a)should pharmacists use the appendices in USP 797 as a guide or b)should pharmacists refer to the checklist in the PSA Professional Practice Standards Standard 11? 3. Re section 4 of the proposed guidance,If I choose to follow USP chapter 797(rather than PIC/S) where will I be able to get training about this document. Will the Pharmacy Board run seminars? 4. Re section 5 of the proposed guidance-the self-assessment section of the revised document

	refers to ”authorised entities audit compliance in some jurisdictions:” In the case of pharmacists choosing to follow PIC/S would the TGA be the authorised entity? If, however, a pharmacist choses to adopt 797, then a TGA auditor has no jurisdiction in a community pharmacy. Would an auditor, who understands compounding and USP 797, come from the Pharmacy Board.? In Australia, the USP has only previously been used as a general reference but not as a specific practice standard. Pharmacists largely are unaware of the USP guidelines, and are not taught this in the course of normal pharmacy training. The APF has no formulations for compounded parenteral preparations. How can I be sure that I will be fairly treated during an audit? How will I know that the auditor has specific expertise in this area (USP 797) and will not audit me as if I am a manufacturer?
5. Do you have any suggestions on how the proposed guidance could be improved (e.g. any content that should be changed, added or deleted), while still being in accordance with the public interest?	1. This guidance was originally positioned in the Pharmacy Board Guidelines on Compounding of Medicines. It is noted that this guidance replace the section on page 8 of that document. If that is the case, then presumably there will be no timeframe set for affected pharmacists to implement changes to their work practices and are therefore immediately likely to be in breach. PCCA would like to suggest that this document should appear as an annex to the original Board Guidelines on compounding of medicines, relevant only for those pharmacists who wish to prepare sterile compounded parenterals. We would also like to suggest that a specific time interval be set (say 24 months) for full implementation of this document. However, pharmacists should be able to show progress towards implementation of this guidance during this time period .

	2. PCCA would like to suggest that in order for pharmacists to be able to conduct an appropriate self -assessment that the Board provides a Self -Audit template for pharmacists to use. Alternately the Board should specifically state that the Appendices in the USP 797 should be used for this purpose. 3. Currently the PSA Professional Practice Standard Section 11 addresses Sterile Compounding. Will this practice standard still be relevant once USP 797 is adopted, or will it still be used in the case of preparation of eye drops and eye ointments. PCCA would like to suggest that the Board makes some mention of this in the proposed guidance document. There is a self-check section in this Practice Standard. Is the use of the self-audit section of this document relevant. 4. The PSA Standard 11 also specifically mentions that "batch manufacturing" is not covered. If this Standard still has place within the proposed guidance document, would the Board clarify/define "batch manufacturing" The nature of sterile parenteral compounding possibly lends itself to small short run "batch manufacturing". This could have significant implications regarding the quality and cost for providing compounded parenterals to the public and may alter a pharmacist's decision to compound sterile products. Eg a patient may require a daily injection, and therefore a pharmacist may need to prepare one month's supply, provided they have appropriate data to support sterility and stability of that product. If the pharmacist has a second request (or more, as is often the case), does this now become "batch manufacturing" if they are all prepared at once.
6. Do you have any other comments on the proposed guidance?	How soon does the Board anticipate that this Guidance Document will be ready for release?

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