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

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
Organisation name: Kingsway Compounding [redacted]
Contact name: Karl Landers or George Dimaris [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?	Mostly, but please see comments below.
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- they have been addressed.
3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?	Yes- revised guidance supports patient safety.
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-please see below and answers to question 5. A. How long will Compounding Pharmacists have to implement these changes? B. How will the self-audit work? Will the Board make a template available to us or will we use the USP 797 appendices as a reference? Does the PSA Professional Practice Standard number 11 have any relevance here? C. For Section 4 of the proposed guidance, will the Board provide any training or conduct any seminars regarding USP 797 or PIC/S? D. For Section 5 of the proposed guidance- there is a reference to "authorised entities audit compliance in some jurisdictions" in the self-assessment section. Could you please clarify who the authorised entities will be? And would these entities be the same for pharmacies following USP 797 and those following the PIC/S? Would those pharmacies adopting USP 797 be audited by the TGA, who have no jurisdiction in community pharmacy? Would the auditor be appointed by the Pharmacy Board? And would the auditor understand compounding and specifically USP 797?

	There is no formal training or teaching of USP guidelines in Australia in the course of normal pharmacy training, and the latest APF has no formulations for compounded parenteral preparations. We need to ensure that the person(s) auditing us will be auditing us on USP 797 only and not treating us as manufacturers- this is only fair.
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?	A. Our suggestion is that Pharmacists who compound parenteral preparations be given ample time for the implementation of this document. We would like to suggest implementation within 36 months. B. We suggest that the Board provide a Self-Audit template for pharmacists to use, so everybody is on the same page, so to speak. C. For patients requiring daily injections of a certain product, pharmacists may need to provide a few week's supply of a product. If the pharmacist can supply sterility and stability testing data, will this be allowable under the new guidelines? This could have implications in terms of accessibility of particular medicines for patients.
6. Do you have any other comments on the proposed guidance?	When does the Board envisage that this guidance document will be released?

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