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: Eastern Health **Contact name: Mazdak Zamani** **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, it has.
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, the shelf life of compounded sterile products as per USP 797 (category 2) seems to be sufficient for provision of accessible compounding services.
3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?	Yes, it does. Both USP and PIC/S are well-regarded international references for provision of sterile compounding services. However, apart from recommendation for self-assessment, there is no clear guidance as to which Australian Regulatory body is responsible to undertake auditing and assess compliance of non-TGA licensed Australian compounders with the above mentioned guidelines.
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?	1- Can I use a combination of all three references (USP 797, PICS for Healthcare Establishment & GMP) in my practice? or do I have to pick the most relevant to my practice and mainly adhere to that one? 2- Can I use USP 797 for assigning shelf life to my products but not follow the guidelines included in this reference?
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?	The inclusion of the *PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010-4)* and *the USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations* is a major improvement in making the guidance relevant to pharmacy compounding services. However, the Board should consider selecting one 'primary' reference and two 'complementary' references. In my opinion, using USP to assign extended shelf life to compounded sterile products and then using a different reference throughout the compounding process is problematic. I suggest the Board highlighting USP 797 as the 'primary' reference and the other two as the 'complementary' references.
6. Do you have any other comments on the proposed guidance?	Please allow a transition period of at least six months from the date of release of the revised guidelines before enforcing the guidelines.

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