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: Pharmaceutical Society of Australia
Contact name: Dr Lance Emerson, Chief Executive Officer
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?	**Terminology.** A concern has been raised with PSA regarding a possible lack of clarity of terminology. It was felt that the Board's use of the term "expiry" appeared to correlate with the "beyond-use date" (BUD) terminology of the USP standard (*USP—NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations*), noting that these two terms are not identical. It has been brought to our attention that in the USP standard BUD does not include the time after the preparation is 'connected' to the patient (i.e. excludes 'hang time') whereas "expiry" is inclusive of 'hang time'. This may have an impact on patient care and therefore clarification of these terms would be helpful.
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?	No further comment.
3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?	No further comment.
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?	See below under Question 6 and *Ongoing communication.*
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?	No further comment.
6. Do you have any other comments on the proposed guidance?	**Current review of the USP standard.** In our previous submission to the Board (November 2015), PSA indicated it was aware that the relevant standard, *USP—NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations*, was being reviewed and revised. We therefore flagged the possibility that the final outcome of the Board's current review may need to be considered with regards to the impact it may have on the use of the standard by Australian pharmacists. While this does not preclude the Board from nominating this as one of the standards that pharmacists must comply with, several major changes proposed in the review of the USP standard have been

	brought to PSA's attention more recently, including: • the collapsing of contamination risk levels of compounding sterile preparations (CSP) from three (low-, medium- and high-risk level) into two categories (Category 1 and Category 2) based mainly on the conditions under which they are made and the time within which they will be used • introduction of a new term "in-use time" to refer to the time before which a manufactured product or CSP must be used after it has been opened or punctured. These changes may have additional implications for Australian pharmacists and therefore should be taken into account. **Implementation.** PSA believes that a reasonable transition period may be required for pharmacists to become compliant with standards designated by the Board, in particular with the USP standard currently under review. **Information technology.** PSA has received advice that the USP standard appears to be silent on the use of information technology. We are advised that PIC/S includes GAMP certification of computer systems which can be a very time consuming and expensive requirement. Clarification on the use of IT systems and the validation of their processes may be helpful in the implementation stage for pharmacists. **Ongoing communication.** PSA believes that further questions will arise regarding the interpretation and implementation of USP and PIC/S standards in the Australian environment. We would encourage the Board to publish 'questions and answers' for pharmacists to be able to access in an ongoing manner.

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