# 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** |
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| **Organisation name: Southwest Hospital Pharmacy & Joondalup Hospital Pharmacy**<br>**Contact name: Travis Bailey & Chris Shenton**<br>**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

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| **1. Has the proposed guidance been expressed clearly?** | The proposed guidance has been expressed clearly. |
| **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?** | To the extent that the new guidelines indicate the process pharmacists need to follow, to allow a validation method for extended expiry dates, they address concerns. |
| **3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?** | The application of the requirements of USP <797> on sterile compounding will help ensure 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?** | • Clarification is required on the expected timeframe for compliance with these guidelines.<br>• There will be many questions regarding implementation and interpretation of guidelines presented in USP <797> and PIC/s. In this case there should be a method of publishing clarifications that are made to all interested parties so that the body of knowledge of accreditation requirements grow for all.<br>• Clarity may be required as to the application of Australian standards for cleanrooms, isolators and biological safety cabinets. Where there is conflict which standard or guideline should be observed?<br>• The USP <797> appears to be silent on the use of information technology. PIC/s requires GAMP certification of computer systems which is a very time consuming and therefore expensive requirement. Clarification on the use of IT systems and the validation of their processes would be helpful in implementation. |
| **5. Do you have any suggestions on how the proposed guidance could be improved (e.g. any content that should be changed,** | There is no indication in the draft guidance on transition arrangements and time to comply. The Board needs to give pharmacists adequate time become compliant: |

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| **added or deleted), while still being in accordance with the public interest?** | • There exists a deficiency of consultants in Australia with expertise in USP <797> and/or PIC/S<br>  o In the case of PIC/S, although there may be expertise on a manufacturing level, application of this to a small scale setting like pharmacy may take some adjustment<br>• A current deficiency of formalised training in Australia for non-skilled pharmacists and technicians in this area.<br>• Allow professional bodies to enhance practice standards and guidelines.<br>• Lead times required to make physical changes to pharmacy premises to ensure compliance. Factors that need to be considered here:<br>  o The need for large capital expenses (such as fit-outs, purchase of LAFC, monitoring equipment) requiring detailed economic evaluation and (in particular in the public system) time to seek expenditure approval and tendering.<br>  o The time needed to make application to and seek approval from the state based authorities that oversee registration of pharmacy premises.<br>  o Time to achieve validation and certification of processes<br>  o Lead times for purchases of specialised compounding equipment, likely all of it manufactured outside Australia. |
| **6. Do you have any other comments on the proposed guidance?** | Of particular issue is the current revision of USP <797> being undertaken. The revision process began July 2010 and was completed in 2015. The earliest that the revised General Chapter <797> may be published is on November 1, 2016 in USP 40-NF35 with the earliest official date of May 1, 2017.<br><br>Our concern is that any implementation time that falls before the next revision of USP <797> is released, will only increase risk and add compliance cost to the transition for pharmacists.<br><br>There are some major changes proposed to the chapter, including:<br><br>• "*Collapsing of the three compounded sterile preparation (CSP) microbial risk categories (e.g. low-, medium-, and high-risk) into two categories (Category 1 and 2) distinguished primarily by the conditions under which they are made and the time within which they are used.*"<br>• *"Introduction of the terminology "in-use time" to refer to the time before which a conventionally manufactured product used to make a CSP must be used after it has been opened or punctured, or a CSP must be used after it has been opened or punctured."*<br><br>The USP has stated that facilities in the US that compound according to USP <797> will have a 6-month period with which to comply with the changes in the new revision, which could be extended by the committee. It may be worthwhile highlighting that this 6-month period is for pharmacies already compliant with the current revision. It would therefore not seem unreasonable to allow Australian pharmacies a 12- |

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| | month window to compliance after the release of the new revision. |

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