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: The Society of Hospital Pharmacists of Australia **Contact name: Kristin Michaels** **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?	SHPA believes that the clarity of the revised guidance is hindered by a lack of detail in the parent document with respect to: ▪ the expected use of guides / standards [such as the *PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010-4)*, the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 009-8)* and *the USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations*] to guide the compounding of all medicines ▪ the development standard formulae, standard operating procedures and master worksheets which requires an evidence-based approach to describe the quality of evidence to support decisions, the environment and equipment required, the skill of the operator required, expiry date justification and quality control requirements for compounded products ▪ the compounding of other parenteral products (e.g. eye drops) ▪ when a compounded product falls into to more than one category e.g. sterile injectable medicines prepared as a batch, or sterile injectable medicine prepared in accordance with the manufacturer's instructions that requires an extended expiry date We suggest that future versions of this guideline should include such detail to provide context and clarity. SHPA also suggests that the placement of the revised guidance should be reconsidered and that it should be moved to the end of section 6. This would ensure that the reader would understand the guidance with respect to products *manipulated in accordance with the manufacturer's instructions*, *modification of commercially available products* etc. prior to reading about guidance on expiry dates for this sub-set of products.
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.
3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?	In the main, 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?	Not if the changes proposed by SHPA are incorporated to improve clarity.
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?	Introduction ▪ SHPA believes that for clarity this guidance should be titled "Compounding of sterile injectable medicines" rather than parenteral medicines as the word "parenteral" has an accepted international definition (i.e. not oral). The guidance should refer throughout to "sterile injectable medicines" rather than parenteral medicines. This would clarify that this section does not apply to dose forms such as eye drops (although SHPA does not support this approach). ▪ The definition should clarify if the revised guidance applies to a product described under *Manipulation of products in accordance with manufacturer's instructions* if an expiry date different to that specified by the manufacturer is being considered Self assessment and audit ▪ We remain concerned that this section does not distinguish between the responsibilities of individual pharmacists and the pharmacy service or team including the use of pharmacy technicians. Expiry of compounded parenteral medicines ▪ This section should refer throughout to "sterile injectable medicines" rather than parenteral medicines. ▪ The first sentence implies that the guidance only applies if a sterile injectable medicine is prepared for a specific patient, is this the intent? Assigning expiry dates to compounded parenteral medicines ▪ This section should refer throughout to "sterile injectable medicines" rather than parenteral medicines. ▪ SHPA suggests that in addition to the default expiry of 24 hours, reference is made to the maximum expiry dates listed in the *USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile*

	Preparations ▪ First dot point – We believe this sentence is open to interpretation as meaning of "contamination risk level" is not defined. The *USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations* discusses multiple factors that must be considered together to identify an expiry date for a specific product (e.g. environment and equipment required, the skill of the operator required, standard operating procedures described and quality control requirements). This could be expressed as assessment in line with *USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations.* ▪ Third dot point – as sterility cannot be 'maintained', SHPA suggests that this sentence be changed to "…will remain physically, chemically and microbiologically stable when stored under…"
6. Do you have any other comments on the proposed guidance?	SHPA notes that the *USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations* and the *National Competency Standards Framework for Pharmacists in Australia* are currently undergoing review and that the outcome of these review may affect content of the Guideline. We suggest that when these reviews are finalised that the PBA re-assesses the Guidelines in full.

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