



## Public consultation on the draft *Guidelines on compounding of medicines*

28 April 2014

### Responses to consultation questions

Please provide your feedback as a Word document (or equivalent)<sup>1</sup> to [pharmacyconsultation@ahpra.gov.au](mailto:pharmacyconsultation@ahpra.gov.au) by close of business on Monday 30 June 2014.

#### Stakeholder Details

If you wish to include background information about your organisation please provide this as a separate word document (not PDF).

<b>Organisation name</b>
The Society of Hospital Pharmacists of Australia
<b>Contact information</b> (please include contact person's name and email address)
Karen O'Leary [REDACTED]

#### Your responses to consultation questions on the draft *Guidelines on compounding of medicines*

1. Do the draft guidelines clearly differentiate between simple compounding and complex compounding?
<p>Whilst the guidelines clearly differentiate between the two categories there is a specific group of medicines that cannot be easily categorised using the proposed definitions. They are those medicines that must be reconstituted prior to administration for injection, such as antibiotics. The preparation of these products according to the manufacturer's product information should not automatically be considered as complex compounding just because, ideally, they are prepared using aseptic technique and results in a sterile product.</p> <p>The TGA does not define "aseptic transfer in accordance with manufacturer's instructions" as 'manufacturing'. In addition where a nurse or doctor performs this manipulation it is not considered 'compounding' we would suggest that "aseptic transfer in accordance with manufacturer's instructions" should not be automatically be categorised as 'complex compounding'.</p>

<sup>1</sup> 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](http://www.ahpra.gov.au/About-AHPRA/Accessibility.aspx).

If the intent is to include all such activities as complex compounding it will lead to considerable additional workload as each manipulation will require the generation of a worksheet, additional data recording etc. SHPA is concerned that by making a pharmacy-based reconstitution service less efficient many hospital pharmacy services will be directed to minimise this service and work practices will return to the doctor or nurse reconstituting medicines at the bedside. We do not believe that this is in the public interest.

2. Do the draft guidelines clearly outline which requirements apply to pharmacists who undertake either or both types of compounding (simple and/or complex compounding), and which requirements apply only to pharmacists who undertake complex compounding?

Yes

3. Is the content of the draft guidelines helpful?

Yes

4. Is there any content that needs to be changed, added or deleted in the draft guidelines?

*Demonstrating competence to undertake complex compounding*

We believe that this section is unclear with regards to training programs, specifically if the training program is a 'once off' or annual requirement for pharmacists and other pharmacy staff.

Whilst there is a limited range of training programs regarding compounding techniques SHPA is unaware of any training program regarding the evaluation of the need for a specific compounded medicine and critical analysis and evaluation of information that supports the formulation and advice on storage conditions and shelf life and administration of compounded medicines routinely provided suitable for hospital pharmacists managing a compounding service. (The range of training programs that are advertised as being suitable for pharmacists and pharmacy assistants / technicians would not be suitable as by definition they would not include competencies related to Standard 5.1 which is outside the scope of pharmacy assistants / technicians.)

SHPA is also unaware of any training program that would satisfy the requirement of an annual / routine training program suitable for hospital practice. This is usually assessed through an ongoing or routine workplace validation process.

We believe this section needs to clarify the requirements for:

- initial training regarding compounding techniques which would be applicable to both pharmacists, intern pharmacists and other pharmacy staff
- ongoing training or competency assessment regarding compounding techniques which would be applicable to both pharmacists, intern pharmacists and other pharmacy staff and what, if any, link there is to usual workplace validation processes
- initial training / competence for Standard 5.1 which has a focus on decision making regarding the evaluation of the need for a specific compounded medicine and critical analysis and evaluation of information that supports the formulation and advice on storage conditions and shelf life and administration of compounded medicines which would only be applicable to pharmacists
- ongoing competency assessment regarding Standard 5.1 which would only be applicable to pharmacists

SHPA is concerned regarding the onerous additional workload for hospitals if "aseptic transfer in accordance with manufacturer's instructions" is categorised as complex compounding. This would require that all pharmacists who work on-call (therefore potentially be required to undertake an "aseptic transfer in accordance with manufacturer's instructions") would be required to maintain specific CPD regarding complex compounding.

*Formulations for which precedents do not exist*

In addition to our comments on additional competency requirements SHPA would welcome comments on the need for more extensive PII for pharmacists / services that offer advice on the formulation, storage conditions, shelf life and administration of compounded medicines.

SHPA also believes there should be comment on how a pharmacist should manage requests when the consumer is seeking a 'reproduced product'; that is where the consumer requires the same product from a different compounding provider. This is of concern for consumers with chronic conditions taking a high risk medicine (e.g. lithium mixture) and compounded modified release products where changes to the formulation may impact on bioavailability, stability, storage conditions etc.

*Compounding of parenteral medicines in advance*

SHPA believes this section requires clarity as the summary of changes section includes the statement that hospitals are exempt from this requirement. **We note that a default maximum shelf-life of 24 hours is unworkable in the hospital setting.**

We suggest that the default maximum shelf-life of 24 hours should be applied to all parenteral medicines **unless** they are compounded within a facility operated in accordance with the PICCs Standards. These facilities may be within a public or private hospital or a stand-alone facility.

SHPA believes that the Guidelines should not distinguish between services on the basis of ownership or location of the pharmacy and that terms such as 'hospital' are open to interpretation.

*Manipulation of products in accordance with manufacturer's instructions*

In addition to earlier comments SHPA notes that this definition includes the reconstitution of preparations for oral use such as antibiotics suspensions.

*Risk assessment process for compounded products*

Although batch preparation is discouraged SHPA notes that the statements allow batch processing when the pharmacist has multiple orders for the same product.

*4 Supervision of appropriately trained staff*

These statements are equally applicable to intern pharmacists.

*5 Facilities, working environments and equipment*

SHPA understands that the latest version of the PICCs Standards now includes an additional physical zone - existing facilities will not have this physical zone. SHPA suggests that the Board states that the operation of current facilities when operated in accordance with the PICCs Standards is sufficient to meet these Guidelines.

*15 Reference texts for compounding pharmacists*

SHPA should be listed as the author of the *Australian injectable drugs handbook*

5. Do you have any suggestions for questions to be answered in Frequently Asked Questions developed by the Board to support the guidelines?

The FAQs should include questions from the perspective of pharmacists, pharmacy interns and other pharmacy staff that perform the physical compounding of medicines and from the perspective of those pharmacists with a practice area that focuses on the critical analysis and evaluation of information that supports the formulation and advice on storage conditions and shelf life and administration of compounded medicines and the management of such services.

6. Is the purpose of the practice profile clearly explained in the draft guidelines?

Yes but as the practice profile is focused on a community-based role the use of the profile by all training program providers would be inappropriate. SHPA is unsure if all the performance criteria listed are mandatory, we have assumed that they are for the purpose of this submission.

7. Do you have any other comments on the draft guidelines?

SHPA is concerned regarding the requirement that pharmacists involved with complex compounding undertake / complete specific training courses when a suitable course for hospital practice (for initial training and ongoing competence) does not exist.

SHPA believes that the vast majority of hospital-based pharmacists who are involved in complex compounding are competent in this area. We would welcome guidance from the Pharmacy Board on the evidence it will accept regarding the competency of pharmacists already working within this specific practice area in the hospital sector in the absence of suitable training courses.

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