Public consultation on the draft *Professional practice profile for pharmacists undertaking complex compounding*

28 April 2014

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 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).

Organisation name
The Society of Hospital Pharmacists of Australia
Contact information *(please include contact person's name and email address)*
Karen O'Leary [redacted]

Your responses to consultation questions on the draft *Professional practice profile for pharmacists undertaking complex compounding*

1. Does the draft practice profile clearly explain its purpose, and how it should be used in relation to complex compounding?
Yes. However SHPA believes that the document should not be specific for pharmacists "whose sole professional function is to undertake complex compounding" we believe few pharmacists would have such a narrow practice profile. Most would have other responsibilities such dispensing the compounded medicines or managing this aspect of the pharmacy service. SHPA suggests that the profile be presented in two parts, a profile for pharmacists who: ▪ are responsible for critical analysis and evaluation of information that supports the formulation and advice on storage conditions, shelf life and administration of compounded medicines and who may also have complex compounding included in their job description ▪ regularly undertake complex compounding / have complex compounding included in their job description

[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.

We believe the draft competency standards document relates to the first category and may reflect the role and competency requirements for community-based 'compounding pharmacists'.

However this approach is inappropriate for most pharmacists who undertake complex compounding as part of their job description, particularly pharmacists working in the hospital sector. Nor are they appropriate for hospital-based pharmacists who manage compounding services.

2. Is there any content that needs to be changed, added or deleted in the draft practice profile in relation to complex compounding?

Complex compounding training programs
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; and that are suitable for hospital pharmacists managing a compounding service.

SHPA is also unaware of any training program that would satisfy the requirement of an annual / routine training program for hospital-based pharmacists. This is usually assessed through a 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

Competency Standards for Complex Compounding
Domains 1 and 2
As these competencies are mandatory and applicable to all pharmacists in principle they should not altered. We suggest that rather changing the evidence examples from the *National Competency Standards Framework for Pharmacists in Australia* to compounding-specific statements that additional statements be added to the evidence examples where they are required.

Standard 5.1

- Element 1 could be strengthened to cover the requirements for workplace policies and procedures as well as equipment and consumables availability, the management of waste and hazardous waste and the maintenance of facilities for the routine compounding of a product as well as decisions regarding ad hoc products. This is needed to support the activities listed in Standards 5.3 and 5.4.
- Element 1 should include the training, management and competency assessment of pharmacists and non-pharmacists that perform the physical compounding of products under their direct and indirect supervision. It should also include the management of issues / circumstances that would preclude personal involvement in the preparation of cytotoxic products and other hazardous materials.
- Pharmacists who manage complex compounding services in hospitals are also required to manage services from external contractors; we believe that it is worth including a statement regarding the appropriate management of contracted products or raw materials.
- Element 1 should include the management of the recall of any product compounded including appropriate recording to enable the tracking of all products to specific consumers.

- Element 2 could be strengthened to cover decisions regarding the routine compounding of a product as well as decisions regarding ad hoc products.
- Element 3 should be expanded to include the identification of suitable containers, storage conditions, expiry date and details of the method of administration (e.g. to be infused over 4 hours)
- Element 5 needs to be expanded to include the production of master worksheets for products that are routinely supplied which can then be used as the basis for the worksheet each time the product is compounded.

Standard 5.2

- Element 2 should include evidence statements for both simple and complex compounding.

Standard 5.3

- Element 1 needs to include additional performance criteria regarding the management of the work environment (i.e. not just the principles of the operation of a clean room), infection control and cleaning procedures, training and / or supervision of other staff, the management of workplace validation processes for other staff members etc.
- The wording of Element 2 performance criteria 2 should be: (e.g. by ensuring maintenance of the sterility of gloves during the gowning process).
- Element 6 requires greater reference to the quarantine or other quality control activities for products such as sterility testing and operator validation processes where this is required according to the master worksheet or routine quality control activities.
- We suggest use of the term Laminar Air Flow Work Station rather than laminar airflow cabinet.
- The Standard should also include competency for double check processes including how to undertake checking process for work undertaken by another pharmacist or staff under their supervision.
- In principle the performance criteria in Element 3 of Standard 5.4 are equally applicable to Standard 5.3.

Standard 5.4

- Element 1 performance criteria 4 should also include ensuring that all cytotoxic products are packed in a suitable manner to ensure safe transportation.
- Element 2 reference to 'complex compounded products' is not required; it implies there is a category of non-complex cytotoxic products which is inconsistent with the Guidelines.
- Element 4 regarding non-sterile cytotoxic products, even if the final product does not have to be sterile, compounding should occur within a suitable preparation area to protect the operator.
- Element 4 requires greater reference to the quarantine or other quality control activities for products such as sterility testing and operator validation processes where this is required according to the master worksheet or routine quality control activities.
- The Standard should also include competency for double check processes including how to undertake a checking process for work undertaken by another pharmacist or staff under their supervision.

SHPA does not believe that Domain 6 should be included in the profile. It is irrelevant to hospital-based pharmacists and inconsistent with the stated purpose of the practice profile.

3. Do you have any suggestions for questions to be answered in Frequently Asked Questions developed by the Board, to assist pharmacists in using the practice profile for complex compounding?

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 management of a compounding service (e.g. the critical analysis and evaluation of information that supports the formulation and advice on storage conditions and shelf life and administration of compounded medicines).

4. Do you have any other comments on the draft practice profile?

SHPA is unsure if all the performance criteria listed are mandatory, we have assumed that they are for the purpose of this submission.

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