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)[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
OZE-Pharmacy
Contact information *(please include contact person's name and email address)*
Warren Turner [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?
Yes in general. I request that overall consideration be given to Complex compounding under the following differentiated sub-types or categories. Namely 1. Non-sterile (eg.hormone creams, coal tar solutions, oral slow release etc), Sterile Aseptically Compounded Cytotoxic Products (chemotherapy oncology services) and Sterile Aseptically Compounded products (TPN, Parenteral administration, Intra-ocular, Intra-Dural and Epi-Dural etc.)
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?
The draft guidelines deal adequately with the requirements that apply to pharmacists in general.

[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.

There needs to be an expansion of the requirements for the proposed classes of Complex Compounded products taking into account the potential risks and their mitigation. The requirements and Mandated operational standards are required to properly minimise the potential for misadventure and protect the public.

3. Is the content of the draft guidelines helpful?

The content is a good starting point, the guidelines are very general. I put it to the Board that there should be minimum standards mandated for the practice of compounding Aseptic Sterile products.

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

There have been significant cases of misadventure in the United States of America due to contaminated sterile products, this must be avoided in Australia at all costs. I propose the Board must include additional mandated guidelines for complex compounded sterile products prepared by suitably qualified pharmacists. There must be no scope for misadventure caused by the open and unregulated interpretation of complex compounded product expiry dates. Of particular concern are Sterile Aseptic Compounded Products, these products are by their nature significantly vulnerable to catastrophic failures that can have significant potential to cause harm and even death. These risks include microbial contamination, lack of maintained therapeutic potency, potential for tissue damage through route of administration toxicity and a general lack of product stability data. The proposal for the separation of Aseptic Sterile Complex Compounding into two groups is motivated by the primary fact that cytotoxic compounded products are generally used on the day of preparation due to the requirement for patient specific dosing in response to key clinical factors such as blood cell counts, hepatic and renal function. The risks and safety concerns relating to extended storage and stability of cytotoxic compounds are mitigated by their prompt administration.

Aspetic Sterile products that are non-cytotoxic and that have standard therapeutic doses for administration have demonstrated the greatest potential for misadventure due to contamination. In the USA in particular, the Intra-Dural, Epi-Dural and Intra-ocular routes of administration have resulted in death and disfiguration due to the lack of sterility and potential for increased microbial load. To this end I put it that the guidelines for complex compounding must mandate that the maximum expiry date for all aseptically compounded sterile products must be no longer than seven (7) days from compounding. This is necessary and vital to mitigate the potential risks of contamination considering that any potential for storing an Aseptically prepared sterile product puts the public at risk.

When taking into account the definition of Complex Compounding (in the guidelines) which clearly states that "…. a single 'unit of issue' of a product **that is intended for immediate** use by a single patient…." In light of the concerns raised I request that the Board provide a clear expiry date mandate in order to avoid any potential for misadventure through ascribing extended expiry dates. The mandate of an appropriate maximum expiry date to no greater than seven(7) days or other such lessor time form compounding will prevent excessive storage and mitigate the potential risks.

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

No

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

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

These guidelines are a very necessary and highly relevant document at this time, in particular with the rapid expansion of pharmacy compounding. Pharmacists involved in Complex Compounding must understand that Complex Compounding is a highly professional activity of the highest technical order- one that is not simply a substitute revenue source. Best Practice for the provision of Therapeutic Goods is mandated from appropriately licensed manufacturing facilities. Compounding Pharmacies are not required to meet the strenuous standards mandated by the TGA. As such Complex Compounded products cannot demonstrate the quality aspects such as sterility, stability

and extended expiry when produced in a facility without the rigorous standards controlled by the TGA. The Pharmacy Board must mandate certain restrictions to protect the public and ensure compounding remains a limited professional activity in the absence of Best Practice Manufacturing.

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