# 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** |
|---|
| International Menopause Society |
| **Contact information**<br>*(please include contact person's name and email address)* |
| Associate Professor Rodney Baber, President IMS [redacted]<br><br>Professor Susan Davis, Chair IMS Scientific Committee [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 |
| 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 guidelines are clear on the different requirements associated with complex compounding. However, whilst competency may be obtained through training there does not appear to be any body which accepts responsibility for the standard of that training nor any requirement to test competency. By definition, complex compounding requires well developed skills which should be tested before |

[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.

approval is given and which should also be the subject of continuing educational assessment from time to time.
Complex compounding's greatest danger is that powerful substances, such as hormones, will be prepared by people lacking in competence resulting in a product which contains inaccurate doses of hormones with unreliable pharmacokinetics and the ability to cause harm to those for whom they are prescribed.

3. Is the content of the draft guidelines helpful?

Yes but they do not go far enough.

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

There should be a statement that patients should be advised in writing ( on the label of the compounded product) that the compounded product has not been TGA approved. Most patients have no idea that what they are receiving when compounded is not a TGA approved therapy.

There must be tighter control of the prescription of compounded hormones. Multiple hormones are being compounded that are not approved for use in Australia, such as DHEA, pregnenalone, anmal thyroid gland extract and so forth. Dose, pharmacokinetics and safety data for these are completely lacking.

Similarly, pharmacokinetic data for compounded estrogens and progesterone are lacking such that best guess doses are being prescribed with no evidence of adequate endometrial protection, potentially putting women at increased uterine cancer risk.

There should be a requirement that for all compounded hormonal preparations that patients must be provided with a written patient information document stating that " What you have been prescribed is not a TGA approved therapy. This medication has not been tested for efficacy or safety".

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

Is this product TGA approved
Has this product been tested for efficacy and safety
Does the dispenser have board certified approval to dispense this product
What quality control mechanisms are in place to ensure the quality and accuracy of this product

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

Yes

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

We applaud the board for drafting these guidelines which will go some way towards protecting patients from poor practice.
However we continue to have concerns about training, quality and safety and urge the board to take these issues into consideration

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