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
Australia Vets in Industry
Contact information *(please include contact person's name and email address)*
Dr Finola McConaghy [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?
To clarify this and to improve the document adding the below definition of compounding to the Introduction section: "Compounding means the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for immediate use by a specific person in response to an identified need. See definitions section for more details including a description of simple vs complex compounding."

[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.

This is a very useful definition and it is unlikely to be read if only included in the definitions section, suggest to add to the Introduction
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?
See suggested changes at Q4
3. Is the content of the draft guidelines helpful?
See suggested changes at Q4
4. Is there any content that needs to be changed, added or deleted in the draft guidelines?

Suggested change to page 6/21:

The Agricultural and veterinary chemicals code (AgVet Code) specifies that to compound a medicine for animal use, a pharmacist must have received instructions from a veterinary surgeon.

bottom of p6/21

(Note: While the Agvet Code does not require the instruction to be in writing, the Australian Pesticides and Veterinary Medicines Association (APVMA) advises that best practice would indicate the provision of precise written instructions to evidence any transaction. Refer to www.apvma.gov.au for further information).

top of 7/21

Suggest to delete the Note in brackets on top of 7/21 and replace with:
The AgVet Code exempts compounded veterinary chemicals from the requirements of registration, however for each state there is legislation relating to the supply of medicines.
The requirements may vary, for NSW refer to the Poisons and Therapeutic Goods Regulation 2008, see below from this Regulation:
For a pharmacist to supply an S4 to a veterinary surgeon this can only be supplied by a pharmacist on the written prescription of a veterinary practitioner, medical practitioner etc
This legislation describes the form of a prescription required, see Appendix 1 for full list of relevant legislation.

Pharmacists are also permitted to compound veterinary pharmaceutical products provided that instructions been received from a veterinary practitioner as outlined in the Agricultural and veterinary chemicals code (AgVet Code). P 10/21

ADD the next sentence adjacent to the above sentence

"For scheduled medicines this instruction must be in the form of a prescription in NSW, refer to relevant legislation at Appendix 1 for each state for details of requirements for supply of scheduled medicines."

11. Packaging and labelling requirements

Pharmacists should package and label compounded medicines in accordance with the requirements outlined in relevant state and territory legislation and guidelines, the guidance in Guideline 6 Labelling of dispensed medicines of the Board's Guidelines for dispensing of medicines, the practice standards and the information published in the section Extemporaneous dispensing in the current edition of the Australian pharmaceutical formulary and handbook.
p15/21

ADD BELOW:

In the case of veterinary compounding, refer to relevant legislation at Appendix 1, ensure details as per the prescription are included, for NSW these include:

- the date of the prescription,
- the name and address of the animal's owner and the species of animal,
- the drug name, strength and quantity,
- the directions for use shown on the prescription.

In the supply legislation in NSW it is not permitted for a veterinary surgeon to add an oversticker to a compounded medicine for supply to an owner thus all the details as per the prescription need to be included on the label.
It is recommended to remind the veterinary surgeon that the product should be supplied without an oversticker.

12. Counselling

Pharmacists should ensure that every patient or their agent are offered counselling on each occasion a compounded medicine is supplied (refer to Guideline 8 Counselling patients about prescribed medications of the Board's Guidelines for dispensing of medicines). This should be achieved by face-to-face contact whenever possible. When this is not possible, for example because of indirect supply of the compounded medicine to the patient, pharmacists should ensure they comply with Guideline 4 Internet, mail-order dispensing and other indirect supply of medicines of the Guidelines for dispensing of medicines.

p 15/21

ADD BELOW SENTENCE:

In the case of veterinary compounding the pharmacist should ensure that the animal owner is aware that a compounded medicine is being used, in particular if a similar registered product is available.

ADD sentence below to section on

Adverse reactions

Pharmacists should report adverse reactions to veterinary compounded medicines to the APVMA. See http://www.apvma.gov.au/use_safely/index.php Although this reporting system is for registered veterinary medicines the APVMA will accept reports relating to non-registered products.

Recommend to add section re Expiry dates, see suggested text below

Expiry dates:
Compounded products are "intended for immediate use" thus it is not appropriate to assign long term expiry dates. It is recommended to assign an expiry date of 28 days from the date of manufacture unless specific evidence is available to support a longer expiry date.
Specific evidence should be in the form of stability data which should include stability testing on at least 3 samples stored under controlled conditions and tested at the date of manufacture, 1 month, 3 months.. up until the date of expiry assigned. Testing should include a full range of specifications including assay, sterility… depending on the nature of the product.

In the second draft document "draft Professional practice profile for pharmacists undertaking complex compounding" on page 12 of 47 states the below:
Standard 1.1 Practise legally Element 1:

Ability to describe the key requirements of the Australian Pesticides and Veterinary Medicines Authority (APVMA) Advertising Code and product registration requirements as they apply to complex compounded products for veterinary use.

There is no "APVMA Advertising Code" change this to the AgVet Code and refer to the APVMA fact sheet on compounding.

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?

See comments at Q4
7. Do you have any other comments on the draft guidelines?
See comments at Q4

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