



The Australian Veterinary Association

Submission to the Pharmacy Board of Australia – Public consultation on the draft *Guidelines on compounding of medicines*

30 June 2014

Pharmacy Board of Australia

Please provide your feedback as a Word document (or equivalent) to pharmacyconsultation@ahpra.gov.au by close of business on Monday 30 June 2014.

Introduction

The Australian Veterinary Association (AVA) is the national organisation representing veterinarians in Australia. Its 8000 members come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, farm animals, including cattle and sheep, and wildlife. Government veterinarians work with our animal health, public health and quarantine systems while other members work in industry for pharmaceutical and other commercial enterprises. We have members who work in research and teaching in a range of scientific disciplines. Veterinary students are also members of the Association.

We welcome the opportunity to comment on the draft Guidelines on compounding of medicines on behalf of AVA members.

Discussion Paper Responses

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).

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| Organisation name |
| Australian Veterinary Association (AVA) |
| Contact information |
| <i>(please include contact person's name and email address)</i> |
| Dr Bruce Twentyman  |

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

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.

1. Do the draft guidelines clearly differentiate between simple compounding and complex compounding?

The AVA is comfortable with the definitions that give the distinction between simple compounding and complex compounding, however the use of the phrase in the simple compounding definition, “immediate use by a specific person”, does not cover an animal patient. As the guidelines clearly make reference to veterinary compounding we feel that animal patients should be referenced in the definition or at least acknowledged.

In the complex compounding definition, it refers to “immediate use in a specific patient”. This could mean an animal patient of a veterinarian, but it would clarify the definition to ensure compounding for a veterinarian’s patient was also covered.

The AVA would also suggest that the emphasis on “immediate use” be highlighted in both definitions to alert pharmacists of the dangers of;

- enhanced chemical instability of the compounded product
- increased likelihood of microbial contamination of the compounded product, and
- increased likelihood of dose administration errors associated with the compounded product.

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 make it clear there is a Pharmacy Board of Australia’s view that there is a distinct difference between simple and complex compounding.

In reference to veterinary compounding it should be stressed that the pharmacist needs to work very closely with their veterinarian as there are complex species differences in veterinary medicine and the compounding pharmacist would not be expected to be fully cognisant with these differences.

The AVA would recommend that compounding pharmacists practicing veterinary compounding should complete extra training through organisations such as the Professional Compounding Chemists of Australia (PCCA) and have frequent discussions with their prescribing veterinarian to build a genuine pharmacist – veterinarian relationship.

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?

4.1: Circumstances where it may be inappropriate to compound a product.

The PBA Guidelines for dispensing of medicines; 5. Extemporaneous dispensing (Compounding) state;

“An extemporaneous preparation should be used only in circumstances where a commercial product is unavailable or unsuitable.”

The AVA strongly supports this original guideline and the inclusion in the new guidelines on p. 10 of the consultation paper. There is one difficulty that the AVA has and that is where a compounding veterinary pharmacist can make a minor adjustment to the concentration / preparation of a pharmaceutical product and claim that this product is different from a readily available registered veterinary pharmaceutical, thereby nullifying the above guideline.

This creates a mechanism that could be utilised to bypass existing TGA and APVMA exemptions to, in effect, copy existing registered products. This has the potential to undermine the regulatory process of veterinary medicine registration through the Australian Pesticides and Veterinary Medicines Authority (APVMA) and creates a disincentive for pharmaceutical companies to invest in research and development of veterinary medicines. Registrants of veterinary medicines must provide safety, efficacy and stability data to the APVMA which is not required with a compounded product as they are considered unregistered veterinary medicines.

The AVA suggests a tightening of the guideline to include;

“An extemporaneous preparation should be used only in circumstances where a commercial product is unavailable or unsuitable and would not be deemed a close formulation of an available and suitable commercial product.”

4.2: Compounding in anticipation

The compounding veterinary pharmacist must be aware of the legislation that governs veterinary compounding. The APVMA has released a factsheet; Compounding Veterinary Pharmaceutical Products, May 2013 that states;

“Exceptions for compounding

Veterinary pharmaceutical products compounded by a pharmacist are expressly defined as not being veterinary chemical products and do not require registration provided that:

1. the compounding of the product is undertaken in accordance with the instructions² of a veterinary surgeon³;
2. the pharmacist⁴ (or another competent staff member supervised by the pharmacist) prepares the product in the course of the profession of pharmacy as permitted by or under a law of the state or territory in which the pharmacist is practising or a law of the Commonwealth other than the Agvet Code.

This exception will **not** apply to the preparation of a veterinary pharmaceutical product **in anticipation** of a veterinary surgeon's instruction. Such a compounded product would be an unregistered veterinary chemical product, and its preparation without an APVMA licence to manufacture veterinary chemical products could constitute an offence, attracting a penalty of up to 240 penalty units⁵ (i.e. \$40,800 for an individual), or \$204,000 for a company for each instance. Possession of unregistered veterinary chemical products with the intention of supply could also constitute an offence, attracting a penalty of up to 200 penalty units (i.e. \$34,000 for an individual), or \$170,000 for a company for each instance. Any subsequent supply without evidence of an instruction from a veterinary surgeon could also be an offence carrying a penalty of up to 300 penalty units (i.e. \$51,000 for an individual), or \$255,000 for a company for each instance.

www.apvma.gov.au

4.3: Advertising of bulk compounded product to veterinarians and ignoring the definition of a

² While the Agvet Code does not require the instruction to be in writing, best practice would indicate the provision of precise written instructions to evidence any transaction.

³ The Agvet Code refers to 'veterinary surgeon'. Some state/territory legislation refers to 'veterinary practitioner', which has a similar meaning. The veterinary surgeon/practitioner must be registered in accordance with relevant legislation in the state/territory in which the diagnosis was made and the prescription/instruction written.

⁴ A pharmacist must be registered with the Pharmacy Board of Australia as a practising pharmacist at the time the veterinary pharmaceutical product is compounded.

⁵ The value of a penalty unit is set by Section 4AA of the Crimes Act 1914 and is currently \$170, and companies may be fined 5 times that applying to individuals.

compounded therapeutic product as stated in the guidelines;

“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. For the purposes of these guidelines, the practice of compounding is classified as either simple or complex compounding. Unless otherwise stated, the guidance provided in these guidelines applies to both simple and complex compounding”.

This practice could be seen as collusion to produce bulk compounded product that could be redirected to multiple patients in anticipation of a future need, which is against the TGA exemption for extemporaneous dispensing.

The pharmacist needs to be aware of the required therapeutic course to treat veterinary conditions. There is a requirement to compound only the amount of therapeutic product to treat a specific animal at a specific time for a specifically diagnosed condition. This can be determined in consultation with the veterinarian and should be clearly noted on the prescription. Oversupply for future use may encourage use on other than the specific patient and may mean a therapeutic product is used beyond the expiry date. If a prescription is ongoing, the pharmacist should be making up single units of issue on a regular basis.

Suggestions:

- I. Tighten the wording of the guideline as to when an extemporaneous product should be used as above.
- II. Add a definition and description of “compounding in anticipation” in the veterinary section, taking note of the APVMA’s factsheet.
- III. Add in the guidelines that the pharmacist has a duty of care to compound only the amount of therapeutic product for immediate use to treat a specific patient at a specific time to ensure they are compliant with TGA and APVMA exemptions.
- IV. A written prescription is required from the veterinarian to the compounding pharmacist.

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

From a veterinary perspective:

1. When a veterinarian requests a compounding pharmacist to fill a prescription, can the medication be returned to the veterinarian to dispense to the client?
2. If a prescription for a compounded medication is sent to a compounding pharmacist, does the compounding pharmacist have an obligation to inform the veterinarian if a suitable registered medication is available?
3. I have written a prescription for a compounding pharmacist to supply a compounded veterinary pharmaceutical product for a specific patient under my care. Am I able to request a number of this compounded veterinary medicine as I know I will probably be seeing similar cases in other animals in the coming week?
4. If a prescription for a compounded medication is sent to a compounding pharmacist, does the compounding pharmacist have an obligation to inform the veterinarian if a suitable registered

medication is available?

5. How long will my compounded veterinary medicine last until expiry?

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?

1. It would be good if it could be emphasised that breaches of the PBA Guidelines are enforceable as they are considered best practice by the Pharmacy Board and could jeopardise registration.

2. On a compounding pharmacist's registration it should clearly state that to compound in bulk for veterinary use requires an APVMA license to manufacture.

3. The AVA would like to suggest that the Australian Veterinary Association: Guidelines for the preparation and use of compounded pharmaceuticals be referenced in the new Pharmacy Board of Australia guidelines. A copy has been attached with this submission.

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