



Animal Medicines Australia  
ABN 76 116 848 344 | ACN 116 848 344

8 July 2014

**Michelle Pirpinias**  
Senior Policy Officer  
Pharmacy Board of Australia  
c/o Australian Health Practitioner Regulation Agency  
GPO Box 9958  
Melbourne VIC 3001

**By email:** [pharmacyconsultation@ahpra.gov.au](mailto:pharmacyconsultation@ahpra.gov.au)

[Redacted]

Dear Ms Pirpinias,

**Re: APVMA draft regulatory guidelines**

On behalf of Animal Medicines Australia, I provide the attached submission in response to the Pharmacy Board's draft *Guidelines on compounding of medicines*.

Please do not hesitate to contact me or Animal Medicines Australia's Director of Corporate Affairs and Regulatory Policy, Mr Michael Wright, if you should require any further information in relation to any aspect of this submission.

Yours Sincerely,

A handwritten signature in black ink, appearing to read "Duncan Bremner", written over a horizontal line.

Duncan Bremner  
**Chief Executive Officer**



**SUBMISSION IN RESPONSE TO  
THE PHARMACY BOARD OF AUSTRALIA'S  
CONSULTATION ON DRAFT  
*GUIDELINES ON COMPOUNDING OF MEDICINES***

8 July 2014



**Animal  
Medicines**  
Australia

## INTRODUCTION

Animal Medicines Australia is the peak industry body representing the animal health industry in Australia. Animal Medicines Australia member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal and livestock sectors. In the livestock sector, member company products are improving agricultural yield while delivering improved environmental, health, safety and animal welfare outcomes. In the companion animal sector, veterinary medicines produced by member companies are facilitating longer, healthier partnerships between humans and animals. Animal Medicines Australia works closely with a variety of industry organisations to promote an evidence based approach to public policy. Animal Medicines Australia is a member of the International Federation for Animal Health.

Animal Medicines Australia and its member companies promote the responsible use of all veterinary medicines. Responsible use entails using products as little as possible and as much as necessary, for the correct duration and in accordance with the APVMA-approved usage pattern. Animal Medicines Australia and its member companies participate in industry stewardship activities including **drumMUSTER**, ChemClear® and Agsafe Accreditation and Training.

## RESPONSES TO CONSULTATION QUESTIONS

### Stakeholder Details

*If you wish to include background information about your organisation please provide this as a separate word document (not PDF).*

<b>Organisation name</b>
Animal Medicines Australia
<b>Contact information</b> <i>(please include contact person's name and email address)</i>
Mr Michael Wright Director, Corporate Affairs & Regulatory Policy [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?
Assuming that a pharmacist has been able to determine which type(s) of compounding (simple and/or complex) they are undertaking, the guidelines provide a clear statement of the requirements applicable to her/him.
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?
<b>4.1 Availability and suitability of commercial products</b>
Page 10 of the draft guideline includes the following:

*“A compounded medicine should be prepared only:*

- in circumstances where an appropriate commercial product is unavailable or unsuitable...”*

Animal Medicines Australia supports the recommendation made by the Australian Veterinary Association to amend this guideline to make clear that the legislative exemptions that exist to facilitate compounding do not support the effective substitution of suitable and available registered products. If a compounded product is essentially the same as a registered/commercial product, then minor changes in formulation do not in truth render the compounded product a novel drug. Of course, there will always be questions of degree involved in the assessment of whether a compounded medicine is *essentially* the same as a registered medicinal product. By highlighting the legal risk associated with closely replicating a registered medicinal product, however, the guidelines would discourage the abuse of the traditional compounding function of pharmacists.

#### **4.2 Definitions of “Compounding” and “Simple compounding”**

It is important that the language used in the Pharmacy Board’s guideline reflects the fact that it applies to compounding undertaken for human *and* non-human animal patients.

Accordingly, Animal Medicines Australia recommends that the definition of “Compounding” and “Simple compounding” be amended to include explicit reference to animal patients. At present, these definitions refer to use by “a specific person”, which may give the impression that veterinary compounding is not included within the ambit of the guideline. Express reference to non-human animal patients would assist pharmacists to identify the scope of their obligations under the Pharmacy Board’s guidelines.

#### **4.3 Highlighting the consequences of non-compliance with the Pharmacy Board’s guidelines**

The compounding pharmacist’s enjoyment of exemption from regulation under the Agvet Code is contingent on her or his compliance with professional standards as articulated in documents including the guideline currently under consideration.

If a pharmacist prepares a medicinal product in a manner that does not comply with the Pharmacy Board’s guidelines in relation to compounding of medicines, the law treats the product as a veterinary chemical product for the purposes of the Agvet Code and attaches serious penalties to various dealings with unregistered chemical products. These penalties ought to be directly referred to in the guidelines.

The guidelines should include a clear statement of the present state of the law that prohibits the compounding of veterinary products prior to, or without, instruction from a veterinary practitioner. That is, the compounding pharmacist who prepares a product in the expectation that a veterinary prescription for that product will likely be created at some point in the near future is committing an offence to which serious consequences attach under the Agvet Code. A prior instruction must exist for a compounded substance to be placed beyond the definition of a veterinary chemical product for the purposes of the Agvet Code.

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

5.1 The definition given for compounding needs to be more explicitly stressed in FAQ, i.e. limited to extemporaneous preparation and supply of a single unit for immediate use”. Not to be prepared in wholesale batches, as is the situation with some compounders of veterinary products who are in direct competition with highly regulated GMP-approved manufacturers of approved veterinary pharmaceuticals.

5.2 I am a pharmacist who receives a report of a clinically significant adverse experience relating to a compounded veterinary product. Who do I report this to?

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?

Animal Medicines Australia supports reference being made to the Australian Veterinary Association’s “Guidelines for the preparation and use of compounded pharmaceuticals” within the guideline.