



International  
Animal Health Products  
THE AUSTRALIAN COMPANY

17<sup>th</sup> April 2014

Committee Secretary  
Senate Rural and Regional Affairs and Transport Legislation Committee  
PO Box 6100,  
Parliament House  
Canberra ACT 2600  
Australia

Amendment (removing re-approval and re-registration) Bill 2014

Submission: from International Animal Health Pty Ltd  
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Schedule 2- Re-approvals and re-registrations – repeal heading

Subsection 3(1) of the code set out in the schedule (definition of approval) (b) repeal included re-approval.

**In addition:**

There is a major concern from the veterinary pharmaceutical companies currently with the veterinary compounding industry. Compounding pharmacies are currently preparing products which are closely similar to registered products and supplied to veterinarians as replacements for registered products. This practice is becoming widespread, particularly in the equine and small animal veterinary fields. Veterinary products prepared by compounding pharmacies are not subject to the rigorous controls of registered products. Compounded products are not manufactured under GMP and there are no trials conducted of their efficacy or safety. The use of compounded products is becoming widespread increasing the risk to animal safety. The definition of a veterinary chemical product allows for veterinarians to purchase from a compounding pharmacy any product. If this definition was tightened to exclude products closely similar to registered products this practice would be reduced.



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**Proposed amendments to revised AgVet Legislation:**

**5 Definition of *veterinary chemical product***

- (4) A veterinary chemical product does not include:
- (a) a substance or mixture of substances that is:
    - (i) prepared by a pharmacist in accordance with the instructions of a veterinary surgeon; or
    - (ii) prepared by a veterinary surgeon;  
in the course of the practice, by the person preparing the substance or mixture of substances, of his or her profession as permitted by or under a law of this jurisdiction; **ADD and must not be**  
**(iii) identical or closely similar to a currently registered product; or**
  - (b) a substance or mixture of substances declared by the regulations not to be a veterinary chemical product.

Kind Regards

International Animal Health Pty Ltd