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3 December 2021

Dr Rachel Chay
Registration Management
Australian Pesticides and Veterinary Medicines Authority

By email only: VLCfeedback@apvma.gov.au

Dear Dr Chay,

Re: Revised Veterinary Labelling Code

Thank you for the opportunity to provide comments on the revised Veterinary Labelling Code.

Animal Medicines Australia (AMA) is the peak industry body representing the leaders of the animal medicines industry in Australia. Our members companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products to protect and treat animal illness, disease and injury, and support animal welfare across the livestock, equine and companion animal sectors. AMA members range from local businesses to the local divisions of global companies and includes companies who manufacture in Australia for global export markets. AMA members represent more than 90% of Australian sales of registered veterinary products.

AMA welcomes this update to the Veterinary labelling Code (VLC) and associated guidance material. The VLC was last updated in 2014/15 and a number of errors and inconsistencies that have accrued since then have resulted in ongoing administrative inefficiencies and misunderstandings.

One of the key problems has been the inconsistent use of 'may', 'should' and 'must' in previous VLC guidance. This has made it very difficult for both registrants and assessors to clarify the relevant label requirements, and identify and differentiate mandatory requirements from voluntary requirements, leading to delays in the label approval process.

AMA was pleased to engage with APVMA extensively over the last 18 months to systematically review the VLC to ensure that it provides clear and unambiguous guidance material that correctly reflects the legislated label requirements, identifies the additional label requirements that are required to satisfy APVMA, identifies label content that should be included wherever possible (for example, if the label size permits), and the information that may be included at the discretion of the applicant.

AMA has already provided considerable detailed feedback on the updated VLC during the review process. A small number of additional comments are provided in Attachment 1.

AMA wishes to note that any changes to the VLC arising from this update will not be applied retrospectively to existing labels. Any new labelling requirements that differ from previous VLC versions will only be applicable to labels approved after the implementation date of the revised VLC.

The VLC update has been a major undertaking and AMA wishes to congratulate the Registration Management team at APVMA on reaching the final stages of this important project. We anticipate that the correction of errors and inconsistencies, improved guidance on labelling requirements and clearer communication of those requirements through new web pages will have a significant positive impact for both the regulator and registrants.

We look forward to the new VLC being implemented in early 2022.

If we can provide any further information, please feel free to contact me.

Yours Sincerely,

Dr Charmian Bennett

Director Science and Policy

(unsigned for electronic submission)