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Director, Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority

Submitted by email only: enquiries@apvma.gov.au

Dear Director,

Re: Proposed establishment of active constituent standards as a legislative instrument under section 6E of the Agvet Code

Thank you for the opportunity to provide comment on the proposed establishment of active constituent standards as a legislative instrument under section 6E of the Agvet Code.

Animal Medicines Australia (AMA) is the peak industry association representing Australia's animal health sector. Our members are the global and local innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's \$28 billion dollar livestock industry and the \$31 billion pet industry.

AMA understands that this proposal is essentially an administrative action to provide APVMA with legal authority to enforce active constituent standards. The material content of the existing requirements for active constituents will not change (although some minor typographical errors may be corrected). Further, the new Standard will be updated on a regular basis (similar to the way in which the standard for MRLs is maintained). Regular updates will enable the inclusion of new active constituents and adjustments in response to Chemical Review decisions.

In principle, AMA supports the development of an active constituent standard. AMA notes that this proposal is intended to apply (at least initially) to agricultural active constituents. We would encourage APVMA to designate the new Standard as applying (at least initially) only to active constituents in agricultural chemical products.

In anticipation of a future expansion of the new Standard to apply to veterinary active constituents, AMA would like to offer the following comments and suggestions.

AMA notes that the existing informal standards were established for and are reflective of active constituents in agricultural chemical products. There are, however, numerous active constituents that are used in both agricultural and veterinary chemical products (as well as many active constituents that are exclusively used in veterinary chemical products). These 'dual' actives may be approved for veterinary use based on a pharmacopoeial monograph. However, the proposal notes that an APVMA Standard 'would take precedence' over a pharmacopoeial monograph.

Subsequent advice to AMA by APVMA noted that it is not intended for the new legislative instrument to supersede appropriate and widely accepted industry specifications for veterinary active constituents such as the British, European or US Pharmacopoeia.

AMA therefore notes that the new Standard should specifically provide for the approval of veterinary active constituents based on reference to an appropriate pharmacopoeial monograph, and that such monographs are designated as meeting (and not superceded by) the APVMA Standard.

AMA notes that some actives (most likely to be new actives) may not have a monograph in one of the recognised pharmacopoeia. In such cases, it may be appropriate for APVMA to specify a minimum purity for the active constituent when used in veterinary chemical products.

In summary, a direct conversion of the current informal standard to a legislative instrument is likely to impose an additional regulatory burden to the approval of veterinary active constituents. The inclusion of veterinary active constituents in this new Standard requires additional consideration to prevent unintended consequences.

However AMA acknowledges that this proposal is intended to deliver important improvements for APVMA, and as such, AMA does not oppose APVMA proceeding with the establishment of a new Standard that is designated as applying to the approval of active constituents used in agricultural products *only*.

AMA would welcome further engagement on the applicability of the new Standard for veterinary active constituents, which may subsequently be incorporated into a future update of the Standard.

Should you have any questions in relation to this submission, please contact me at c.bennett@animalmedicines.org.au or 0437 369 765.

Yours sincerely,

Dr Charmian Bennett (*unsigned for electronic submission*)

Director, Science and Policy