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Agvet Reform
Department of Agriculture, Water and Environment
Canberra ACT

Submitted electronically only: haveyoursay.agriculture.gov.au/agvet-reform

Dear Agvet Reform Team,

Re: Consultation on proposed regulations and order to improve access to agricultural and veterinary chemicals:

- *Agricultural and Veterinary Chemicals Legislation Amendment (Miscellaneous Measures) Regulations 2021 and*
- *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2021.*

Thank you for the opportunity to provide comment on the proposed regulations and order to improve access to agricultural and veterinary chemicals, as identified above.

Animal Medicines Australia is the peak industry body representing the Australia's leading animal health companies. Its member companies are the innovators, manufacturers, formulators, and registrants of a broad range of veterinary medicines that protect and treat animal illnesses, diseases and injuries, and support animal welfare, across the livestock, equine and companion animal sectors. AMA members represent more than 90% of Australian sales of registered veterinary medicinal products.

AMA seeks to promote a regulatory environment that grants its members sufficient incentive to innovate and introduce new products that improve and protect animal health and welfare, agricultural productivity, food safety and public health. AMA expects that all regulatory proposals adhere to the

Principles of Best Practice Regulation and Regulatory Impact Analysis, as described by the Office of Best Practice Regulation, Commonwealth Government of Australia.[1,2]

AMA has previously provided comment on the *Board and Other Improvements Bill 2019*. The measures contained in that bill were previously introduced in the *Streamlining Regulation Bill 2018* and the *Operational Efficiency Bill 2017*. Our submissions on these bills are available at:

Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 - Department of Agriculture

Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 - Department of Agriculture

AMA supports, or does not oppose, most key measures contained within the *Board and Other Improvements Bill 2019*. We expect that their implementation will provide minor improvements in operational efficiencies for both registrants and the regulator. However, AMA strongly opposes the creation of a Board for APVMA.

It is noted that there are 5 individual measures in this consultation:

- 2 of the measures support the Agvet Legislation Amendment (APVMA Board and Other Improvements) Bill 2019.
- The other 3 measures are to be included in a ministerial order.

Measures to support the Agricultural and Veterinary Chemicals Legislation Amendment (APVMA Board and Other Improvements) Bill 2019

Extensions to protection and limitation periods

AMA supports this measure in principle. Longer protection and limitation periods for new chemical products, or new uses for existing products, will encourage innovators to bring new products to the Australian market and include more uses on labels, which could reduce the need for permits. This approach is also consistent with that of equivalent overseas regulatory authorities, especially for minor uses and/or minor species.

AMA notes that this measure is intended to apply to agricultural chemical products in the first instance (with prescribed agricultural chemical uses directly related to crop groupings and priority uses), but that it may be expanded to veterinary chemical products or active constituent approvals in the future.

However, as noted in AMA's previous submissions, there is limited application of this measure to veterinary medicines. Unlike crops, animal species are rarely grouped together. Simple groupings of animal species, or generalisations between animal species, cannot be made because the differences in drug pharmacokinetics and pharmacodynamics between species are numerous and often unpredictable. Veterinary applications will continue to need to be assessed on a case-by-case basis to ensure the safety and efficacy of use in each animal species.

AMA would welcome the development of other measures to extend protection and limitation periods that are more relevant to veterinary medicines.

[1] https://www.pmc.gov.au/resource-centre/regulation/best-practice-regulation-guide-ministerial-councils-and-national-standard-setting-bodies

[2] https://www.pmc.gov.au/sites/default/files/publications/australian-government-guide-to-regulatory-impact-analysis.pdf

Approval and registration for prescribed active constituents, chemical products or labels

AMA supports this measure, as it will provide a more efficient method to approve new active constituents, chemical products or labels for low-risk products, where minimal or no technical assessment is required. This measure also represents a better alignment of regulatory effort with risk for low-risk products.

AMA further supports the ability of APVMA to specify the kinds of approvals and registrations that APVMA can determine as either prescribed approvals or prescribed registrations, similar to the existing provisions for prescribed variations to approvals and registration, with appropriate safeguards in place to ensure that only safe and effective products are made available to consumers.

Other regulatory measures

Amending the definition of minor use

AMA supports removal of the condition 'would not produce sufficient economic return' from the definition of 'minor use', thereby making it easier for a minor use permit to be issued for products that are registered for a particular use in Australia, but are not available due to supply chain issues.

AMA notes that this amendment is intended to capture the specific situation where supply chain issues have removed access to a particular product. The permit system should not be used to bypass the registration process or provide access to an alternative product when a registered product is also available. Further, once the supply chain issues are resolved, any associated permits issued using this amendment should be revoked/cancelled.

Standards for minor differences in constituents, concentration, composition and purity

AMA supports this measure in principle. It will provide a more efficient way to accommodate routine, safe variations in constituents that arise during manufacture, but which do not represent fundamental changes in the composition of that product, or affect the quality, efficacy or safety of that product.

AMA supports the ability for APVMA to make a standard for allowable differences from the registered particulars for active and non-active constituents in relation to concentration, composition and purity, where those differences do not represent fundamental changes in product constituents, concentration, composition or purity. If a registration holder wished to vary a product beyond the prescribed extent, a variation application would still be required.

AMA notes the need to consider veterinary products differently to agricultural products, as the majority of veterinary products are manufactured in compliance with the Australian Code of Good Manufacturing Practice (The GMP Code) or equivalent overseas GMP codes, which includes strict requirements for quality assurance and batch consistency. Care is required to ensure that this amendment does not duplicate, replace or contradict existing GMP requirements.

Excluding certain enzyme products from APVMA regulation

AMA does not oppose the addition of certain enzyme products to the list of substances declared not to be a veterinary chemical product and therefore not regulated by APVMA.

These substances may include nutritional or digestive products, and products that are applied topically to the teeth, hair, fur or intact skin of an animal to alter its appearance or odour. Such products should be used solely for cosmetic purposes to mark or otherwise identify a specific individual and should not contain any antimicrobial or antibiotic active constituents, or make any therapeutic claims (other than cosmetic alteration).

Please contact Dr Charmian Bennett (c.bennett@animalmedicines.org.au) if we can provide any further information to assist.

Yours sincerely,

(unsigned for electronic submission)

Ben Stapley

Executive Director