



Animal Medicines Australia
ABN 76 116 848 344 | ACN 116 848 344
18 National Circuit
Barton ACT 2600, Australia
P: +61 2 6257 9022
animalmedicinesaustralia.org.au

19 July 2017

Agvet Chemicals Branch

Department of Agriculture and Water Resources
GPO Box 858
Canberra ACT 2601

By email only: agvetreform@agriculture.gov.au

Dear Agvet Chemicals Branch,

Re: Submission to Consultation on the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

On behalf of Animal Medicines Australia, I write to provide our submission to the *Consultation on the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*.

Animal Medicines Australia is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. As such, we have a strong interest in ensuring that these products can continue to be registered for use in Australia to for the benefit of animal health and welfare, agricultural productivity and public health.

Yours sincerely

Ben Stapley
Executive Director

SUBMISSION TO THE
Consultation on the Agricultural and Veterinary Chemicals
Legislation Amendment (Operational Efficiency) Bill 2017

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Animal
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Australia

Introduction

Animal Medicines Australia (AMA) is the peak body representing the leading animal health companies in Australia. AMA 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, livestock and equine sectors.

Proposal 1 – Clarifying confidential commercial information provisions

Animal Medicines Australia (AMA) supports measures that will have the effect of improving the efficiency and effectiveness of APVMA assessments. This objective must be balanced by the need to protect commercially sensitive information regarding proprietary products.

AMA's expectation is that the APVMA will not disclose CCI to anyone seeking to produce a generic version of an existing product. However, this proposal appears to allow APVMA staff to disclose CCI "where necessary to perform functions or duties, or exercise powers under the Agvet Code." The circumstances in which CCI may be disclosed by APVMA appear unclear at this stage, and we would welcome further discussion with the Government to understand the practical impacts associated with the implementation of this measure.

It also appears that the issuance of notices will not be considered a disclosure of CCI. While AMA understands that the notice itself may not constitute disclosure, AMA seeks assurance that implementation of this measure does not inadvertently result in the APVMA disclosing CCI about a reference product when confirming that a proposed generic product is 'closely similar'.

Animal Medicines Australia would welcome further industry consultation on this proposal.

Proposal 2 – Simplifying reporting requirements for annual returns

Animal Medicines Australia supports this proposal. AMA understands that APVMA will now require (for each registered product) only:

1. current leviable disposal value (\$), and
2. total quantity (a single total value), which can be expressed as either total mass or total volume, or in the units listed by APVMA.

This removes existing duplication from approval holder reporting requirements.

Proposal 3 – Increase the APVMA's flexibility to manage minor errors in applications at preliminary assessment

Animal Medicines Australia supports this proposal and expects that it will increase efficiency of the APVMA's application assessment process. We would encourage the Government to consider whether this could be implemented in a time frame shorter than 12 months.

Proposal 4 – APVMA amendment of the relevant particulars or conditions in a variation application

Animal Medicines Australia supports this proposal and expects that it will increase efficiency of the APVMA’s application assessment process.

Proposal 5 – Timeframe for notifying Food Standards Australia New Zealand (FSANZ) about variations to the Maximum Residue Limit Standard

Animal Medicines Australia supports this proposal and expects that it will increase efficiency of the APVMA’s application assessment process.

Proposal 6 – Enable a person to apply to vary the particulars of a label approval that is suspended

Animal Medicines Australia supports this proposal.

Proposal 7 – Amend the definition of ‘expiry date’

Animal Medicines Australia supports the change of “should not” to “must not” in the definition of expiry date. We agree that veterinary products must not be used beyond their expiry date *unless* approved by the regulator (with the issue of a 91(1A) permit).

AMA supports the change in format from “month and year” to “date”, provided that this does not legally imply that a specific date (ie: *day*, month and year) must be included on the approved product label/packaging. AMA understands that this amendment is a technical change only, and that it will *not* require veterinary chemical products to be re-labelled from their current MMYYYY format.

AMA requests that the term “date” is clearly specified in the legislation as meaning “month and year” only.

Proposal 8 – Add antimicrobial resistance as a specific safety consideration

The veterinary pharmaceutical industry acknowledges its shared responsibility to tackle the development of antimicrobial resistance, as detailed in the National Antimicrobial Resistance Strategy 2015-2019. Animal Medicines Australia considers that assessment of AMR risk to human health is a sensible element of veterinary medicine regulation, and APVMA has long required Part 10 AMR risk data from registrants as part of the safety criteria. It is appropriate that the APVMA has the mandate to assess AMR risk as a safety concern for veterinary chemicals, using an assessment process that balances the need for effective antimicrobial products that support animal health and welfare, while protecting against any adverse risk to human health.

Recent national surveys have shown that Australia already has enviably low levels of antimicrobial use and antimicrobial resistance in animal populations, demonstrating Australia’s success in the mitigation of AMR development. Current regulations and stewardship activities include:

- restricted access to antimicrobial drugs for use in animals (all classes of antimicrobial drugs that are shared by human and veterinary medicine are scheduled as prescription-only and cannot be obtained over-the-counter)

- restrictions on which antimicrobials can be used in animals, especially in food-producing animals (for example, fluoroquinolones cannot be used in food-producing animals)
- restrictions on the use of antibiotics in animals that are classified as Critically Important Antibiotics for human health
- monitoring of antibiotic importation via TGA reporting and declarations of antibiotic sales through APVMA active constituent sales reporting
- ongoing development of antibiotic stewardship programs in the animal health industry, including industry-funded development of antibiotic prescribing guidelines for cats and dogs (complete) and livestock species (in progress)
- industry-funded surveillance studies of antimicrobial resistant organisms in pathogens of veterinary significance
- government-funded surveillance studies of commensal organisms in major food-producing animal species
- Part 10 Special Data provisions in the current Agvet Code which enable the APVMA to request and assess information which “may have regard to such other matters as it thinks relevant” and that has been used to assess information relevant to AMR risk. This section also covers aspects related to food safety (such as residues and dietary exposures) and is of no lesser significance than other sections in assessing the safety of new products.

Regulatory reforms to address AMR require careful consideration of a range of factors, including animal health and welfare, environmental health, human health (especially in homes and workplaces shared with animals), food safety, international trade, and the use of clear and scientifically robust risk assessment approaches to regulatory requirements and assessments. AMA seeks reassurance that this proposal will not create unintended negative consequences for animal health and welfare, human health or international trade, impede access to innovative new products for Australian farmers and pet owners, or result in legislation that moves away from international regulatory harmonisation. AMA would welcome further discussions with Government to ensure that regulatory controls for AMR are appropriate, balanced and consistent with best practice by major overseas regulators, so that products registered overseas remain registerable in Australia.

In summary, whilst Animal Medicines Australia supports the principle of this proposal, we propose that this amendment is moved to Paragraph 5A(3)(b)(i) of the Agvet Code, so that AMR risk *may be considered by APVMA as required*. This is consistent with the requirements of other global regulators, formally reflects what the APVMA has already been doing for many years, and will ensure that no new regulatory inefficiencies are introduced where AMR risk is clearly not relevant (for example, in the assessment of new insulin products for diabetic dogs).

AMA would also welcome further consultation regarding the interpretation of the new AMR safety criteria prior to its introduction to Parliament, to ensure clarity and certainty for AMA members regarding any changes to product registration requirements.

Proposal 9 – Including civil penalty provisions for false or misleading information

Animal Medicines Australia supports this proposal.

Proposal 10 – minor technical amendments to the Administration Act and Agvet Code

Animal Medicines Australia supports this proposal.