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RRAT inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018

Thank you for the opportunity to provide comment to the inquiry regarding the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulations) Bill 2018.

1. Introduction

Animal Medicines Australia (AMA) is the peak body representing the leading animal health companies in Australia. Our members innovate, research, develop, manufacture, formulate and register veterinary medicine products that prevent, control and cure illness and disease across the companion animal, livestock and equine sectors. AMA seeks to promote a regulatory environment that grants our members sufficient incentive to innovate and introduce new products that improve animal health, agricultural productivity, food safety and public health.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates the approval of agricultural and veterinary chemicals in Australia. The APVMA is responsible for implementing the provisions of the Agricultural and Veterinary Chemicals Code Act (the Agvet Code). As a regulator, the APVMA is highly regarded for providing rigorous, risk-based scientific assessment of new and existing veterinary medicines. Effective regulation and responsible use of veterinary medicines:

- supports access to export markets,
- enables producers to maintain high standards of animal health and welfare,
- promotes longer and healthier lives for our valued companion animals, and
- protects public health through the sustainable production of safe and nutritious food.

AMA maintains high levels of confidence in the *effectiveness* of the regulator's scientific decisions and risk-based assessments, which are high quality, appropriate and relevant to the Australian context.

AMA's seeks to support the APVMA to improve its efficiency in maintaining the rigour of its scientific decisions and risk-based assessments. To that end, AMA supports those components of the Streamlining Regulation Bill that will deliver procedural and administrative efficiencies for the APVMA.

2. Comments on amendments in the Streamlining Regulation Bill 2018

AMA has had the opportunity to comment on the measures contained within the bill during the policy development and regulatory reform process. We consider that the bill will offer useful improvements in APVMA efficiency.

For the information of the RRAT Committee, we offer these additional comments on each of the specific measures contained within the bill.

Part 1 - 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 where minimal or no technical assessment is required. This is similar to the existing mechanisms to approve variations to previously approved chemical products, active constituents and labels, with safeguards to ensure that only safe and effective products are made available to consumers. This measure also represents a better alignment of regulatory effort with risk for low-risk products.

Part 2 – Information to be taken into account in determining applications

AMA supports this measure, as it will remove the need for APVMA to issue section 159 notices to request simple clarifying information that requires no technical assessment. This measure will also address the current need for applicants to submit a variation application immediately after an original application has been finalised.

Given the long timeframes for some application types, it is reasonable that applicants will often have more, or updated, information available while the original information is being assessed. Simple clarifying information, such as updated Good Manufacturing Practice certificates or clearer copies of a document already provided, is primarily administrative and does not require technical assessment. This simple clarifying information should not be associated with additional assessment timeframe and associated fees, like those imposed with the issue of a S159 notice or submission of a variation application. In contrast, providing an additional statistical analysis for a previously submitted trial (following a request from the assessor) would genuinely require additional technical assessment, and the additional fees and timeframe for that assessment (associated with a S159 notice or variation application) are thus appropriate.

Part 3 – Limits on use of information

AMA supports this measure in principle. Longer data protection periods will encourage innovators to bring new products to the Australian market and to include more uses on product labels, which may reduce the need for permits. It is also in line with approaches taken by equivalent regulatory

authorities overseas to encourage innovation and improve access to agricultural chemicals, especially for minor uses and/or minor species.

However, this measure has limited application 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.

Part 4 – Computerised decision-making

AMA supports this measure in principle, Computerised decision-making could potentially provide some efficiency gains in administrative activities, such as application completeness checks and keeping applicants updated on the status of their application/s. This measure also aligns the Agvet Code with similar Commonwealth legislation that authorises computerised decision-making, such as therapeutic goods legislation.

However, any computerised decision-making systems and processes will need to be carefully and routinely validated to ensure that the correct decisions are being made, and made consistently, to reduce the need for additional human verification that would thus undermine the efficiency gains offered by an automated decision-making system. AMA strongly suggests that implementation of this measure is guided by best practice principles, such as those presented in the Administrative Review Council's Report on Automated Decision Making (No. 46, 2004).

Part 5- Accreditation of assessors

In principle, AMA supports the provision of a power to create a framework, sanctions and accreditation scheme in the future and if needed, to facilitate the use of external assessors. It would be appropriate for the APVMA to be involved in setting the standards for any such accreditation scheme.

AMA does not have a view on whether the criteria for accreditation should be described in the primary legislation, or within delegated legislation. AMA believes that it is appropriate that the APVMA should be able to specify the requirements for external assessors in terms of their qualifications and experience, insurance, conflicts of interest, and protocols for handling data and other commercially sensitive information.

While AMA supports establishment of a legislative authority, there remain several issues regarding administration, cost and governance of any accreditation scheme. These will need to be carefully considered and subject to close consultation with industry to ensure that any arrangement delivers a net benefit for the community as well as for the regulated industry.

Part 6 – Voluntary recalls

AMA supports this measure. It will provide greater transparency to the end users of Agvet chemicals. In particular, AMA supports that notifications are required for all recalls related to the compliance of products with the statutory criteria (safety, efficacy, trade and labelling), and that notifications by registrants to the APVMA are *not* mandatory for voluntary recalls for reasons that are not associated with the statutory criteria. This approach is the same as that used for food safety recalls in Australia.

Recall notifications must focus on genuine issues which may impact the end users of that product. As such, a reason for the recall must always be provided by the regulator, so that consumers can better understand the actual risks associated with that recall. For example, the risks posed by a product that is recalled due to safety or efficacy concerns are substantively different to those associated with a recall to change a design element on the packaging.

Part 7 – Notification of new information

AMA does not oppose this measure. It will align label approval and variations with existing requirements for active approvals and product registrations. However, AMA does not anticipate that this reform would deliver significant improvements in regulator efficiency.

Part 8 – Definition of a registered chemical product

AMA supports this measure in principle. It will provide a more efficient way to accommodate routine (safe) variations in constituent concentrations 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 would further support an approach that considers veterinary chemical products differently to agricultural chemical products. This is because 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 include strict requirements for quality assurance and batch consistency.

Part 9 – Suspension or cancellation of approval or registration for provision of false or misleading information

AMA supports this measure. Suspension or cancellation of approvals and registrations is an important tool that should be available to the regulator to employ in rare circumstances where false or misleading information has been provided by an applicant.

Part 10 – Supply of registered chemical products with unapproved label

AMA does not oppose this measure, and notes that it addresses an existing inconsistency in regulatory requirements.

Part 11 – Variation of approval or registration during suspension

AMA supports this measure. Permitting an applicant to vary the particulars of a suspended product should deliver small efficiency improvements for the regulator, but significant improvements for applicants seeking to address deficiencies with a suspended product or label. This should assist APVMA to remove a suspension and return a product to market more efficiently.

Part 12 – Safety, efficacy, trade and labelling criteria

AMA does not oppose this measure. However, AMA notes that the APVMA has already taken administrative action that has substantively the same effect at this regulatory reform measure. As such, the likely impact on regulator performance will be negligible.

Part 13 – Annual operational plans

AMA supports this measure. Removing duplication and inefficiencies in the corporate reporting obligations of the APVMA will allow it to ensure that resources are dedicated to its core business of providing high quality, rigorous and timely product approvals and registrations.

Part 14 – Other amendments

AMA does not oppose these measures and notes that they merely remove redundant and unnecessary provisions, ensure consistency with associated legislation, and improve the regulator's ability to conduct internal reviews and respond to any errors in decisions more efficiently.

3. Summary

AMA supports this Bill as a whole. Measures that will result in tangible improvements in the regulator's efficiency are particularly welcomed. These will reduce regulatory barriers to new and innovative veterinary products that will benefit all Australian animals.

The proposed amendments will support the APVMA to deliver its legislated services more efficiently and effectively while providing greater certainty to applicants in their dealings with the regulator.

If I can provide further information, please do not hesitate to contact me.

Yours sincerely

Ben Stapley
Executive Director