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

22 August 2018

Agvet Chemical Regulation Reform Team
Department of Agriculture and Water Resources
GPO Box 858
Canberra City ACT 2601

By email only: agvetreform@agriculture.gov.au

Dear Agvet Chemical Regulation Reform Team,

Re: Submission to consultation on Streamlining Regulation Bill

On behalf of Animal Medicines Australia, I write to provide our submission to the *Consultation on the Agricultural and Veterinary Chemicals Legislation (Streamlining Regulation) Bill 2018.*

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 for the benefit of animal health and welfare, agricultural productivity and public health.

Should you have any comments or questions regarding this submission, please feel free to contact me.

Yours Sincerely,

Ben Stapley

Executive Director

CONSULTATION ON STREAMLINING REGULATION OF AGRICULTURAL AND VETERINARY CHEMICALS

22 AUGUST 2018

Animal Medicines 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 – Provisional registration or variation with conditions for efficacy (provisional registration of chemical products)

In principle, AMA supports this proposal. If used appropriately, it could be a useful means of hastening the entry of new products into Australia. However, it could also be used by a risk-averse agency to indefinitely delay full registration or to impose potentially impossible hurdles for full registration. Therefore, AMA supports this proposal with the following caveats:

1. AMA supports provisional registration that is limited to products where only confirmatory Australian efficacy data is required and where the applicant can provide substantial overseas efficacy data to support label claims. These circumstances would provide a level of assurance that the provisionally-registered product is effective elsewhere, is likely to be effective in Australia, and that the risk from the lack of local efficacy data is relatively low.

   A product should **not** be eligible for provisional registration if there is no substantial overseas data supporting the label claims for which provisional registration is sought. Without this caveat, there is significant potential for provisional registration to be used as a fishing expedition to test potential claims, and/or seek short-term registration when there is no intention of generating the necessary supporting data in future.

2. AMA supports provisional registration only in circumstances where there are very specific efficacy considerations in Australia. This measure should not automatically force products into a provisional registration when there is sufficient overseas data to satisfy local efficacy requirements.

3. AMA supports provisional registration that is limited to efficacy claims which are not approved for other (registered) products already available on the Australian market (i.e. a novel claim on the Australian market).

   If provisional registration was available for efficacy claims common to other registered products, there would be potential concerns regarding competition in the market between products with a common label claim, where that claim is fully approved for some products, but only provisionally approved for other products.

4. AMA supports this proposal, provided that there is a mechanism to allow end users to distinguish between provisionally and fully registered products. This could be (at least partially) addressed by amendments to the APVMA labelling code on wording and layout.

   Provisional registration could potentially also apply to variations for existing registered products when adding a new claim. The product label would need to distinguish between a

new product with provisional registration, and an existing registered product with a new provisional claim.

This would also require public communication to explain the difference between a provisional claim/product and a registered claim/product.

5. AMA supports this proposal on the understanding that other chemical products (i.e. generics) should not be registered based on a provisionally registered chemical product as the 'reference' product.

6. AMA considers it to be appropriate that provisional registration is constrained to applicants deemed to be 'fit and proper' with good history.

   However, this proposal states that if an applicant is unable to provide the data expected, they are no longer a 'fit and proper person'. What if the ongoing efficacy trials simply fail to show the expected efficacy, or fail for other reasons, despite the applicant's best efforts? AMA suggests that this text is amended slightly, so that an applicant's 'fit and proper' status is not adversely affected in such circumstances.

In addition, AMA believes that it is reasonable for the applicant to agree to a project plan with APVMA to provide the additional efficacy data. AMA supports a three-year limit to provide the required local efficacy data, although we would like to suggest that a period of up to five years is allowed in circumstances where the applicant and the regulator agree that substantial long-term studies are required.

However, AMA remains concerned that the possible gains provided by this measure will be overshadowed by the practicalities of implementing it. A provisional registration system will require a significant investment of APVMA's resources, at a time when the regulator is already dealing with significant operational challenges. There will also be resources needed to monitor compliance of products with provisional registration status.

The need to alter the physical labels on products with provisional registrations would be a very costly and burdensome requirement for registrants. The labels would also have to be amended again when the product (or claim) received full registration. The proposal suggests that a sticker system could be used to indicate provisional registration status. However, there are different requirements for this in each state and territory, and the additional effort to obtain multiple approvals and produce multiple packages to suit each jurisdiction would be prohibitive.

In conclusion, whilst we support the principle of provisional registration, AMA is not convinced that this measure will provide tangible and meaningful improvements to market access for our members.

Proposal 2 – An accreditation scheme for assessors in the future (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. If the use of external assessors becomes an option for application, then some form of accreditation is required. It would be appropriate for the APVMA to set the standards for any such accreditation scheme, but

the administration of that scheme (i.e. assessing the assessors) should be external as this is not core APVMA business.

However, APVMA must consider its impact on timeframes – if using external assessment pre-application does not reduce timeframes after application, then it will not be widely used. The recent trial of pre-application assessments (PAAs) will be particularly informative.

The boundaries between, and responsibilities of, the external assessor and the APVMA, must be clearly defined when such an arrangement is used. Applicants would need assurance that the advice of the external assessor would subsequently be followed by the regulator, and thus provide an efficiency improvement. There should also be a reduction in the relevant fees to reflect the significantly lower burden placed on APVMA when an external assessor is used.

AMA is also concerned that this could become another administration strain on APVMA when there are better priorities to focus on, especially if this scheme is not likely to be widely used. This scheme could potentially impose additional costs on registrants, and create an additional layer of project management and oversight that would not necessarily provide any concomitant improvements in performance or standards.

Proposal 3 – Prescribed approvals and registrations (approval and registration for active constituents, chemical products or labels)

AMA supports this proposal, as it will provide a more efficient method to approve new active constituents, chemical products or labels where minimal technical assessment is required. This is similar to the existing mechanisms to approve variations to previously assessed chemical products, active constituents and labels, and represents a better alignment of regulatory effort with risk for low-risk products.

Proposal 4 – Data protection incentives for certain uses of chemical products (limits on use of information)

AMA supports this proposal, as it 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 veterinary medicines, especially for minor uses and/or minor species.

AMA requests further detail on how this may be implemented for veterinary chemical products. In general, a longer data protection period for animal products would be desirable (due to the smaller number of commodity groups in comparison to crop products). However, this proposal would primarily apply to minor species where additional data protection would be of limited value, given that the costs of generating data for new species (i.e. separate to the major species) are substantial and likely to be disproportionate to the commercial return gained, even with additional exclusivity granted by greater data protection.

AMA would welcome further discussions with the Agvet Chemical Regulatory Reform Team to develop an alternative approach to encouraging innovation and minor uses for veterinary chemical products.

Proposal 5 – Prescribe certain information that can be taken into account if provided during an assessment (information to be taken into account in determining applications)

It is not clear what would change with this new provision. It appears to duplicate the existing s159 provision for 'clarifying technical information' by adding the provision that 'additional fees and timeframes may apply'. Therefore, there would be two potential avenues for APVMA to seek further information from applicants – through the s159 provisions with a fixed timeframe, or through this new provision with a flexible timeframe and cost. A simpler approach would be to change the regulations such that the added timeframe and/or fees for s159 notices would be flexible (rather than fixed, as prescribed in the current regulations).

AMA requests further information on what kinds of information would be accepted by APVMA under this proposal. Given the long timeframe for some application types, it would seem reasonable that applicants would have more, or updated, information available while the original information was still being assessed. For example, an updated GMP certificate.

This measure also needs to differentiate between situations where the additional information requested is primarily administrative. There is no need to impose additional fees or timeframes when there is no technical assessment required. For example, the provision of an updated GMP certificate, or missing data pages (eg: due to poor quality photocopying), should not be associated with an additional timeframe or fees. In contrast, the provision of an additional statistical analysis for a previously submitted trial (following a request from the assessor) would genuinely require additional technical assessment and an additional timeframe.

If the intent of this proposal is to allow APVMA to request clarifying information of an administrative nature, then AMA believes it is reasonable to exclude technical assessments from this measure, such as shelf life data.

However, on page 25 of the Consultation document, it states "For example, where the applicant advises, at the time of making the application, that the additional information will be provided before a particular time during the assessment period of the application….". This statement implies that applicants may provide additional information during the assessment period, which they know is not available at the time of submission. This contradicts the intent of the 2014 reforms - to shut down the provision of new data during assessment - and is a key reason why APVMA does not accept additional stability data during assessment. Yet this proposal reads as if it allows just that.

On the basis of these points, AMA reserves its support on this proposal, pending clarification and further information.

Proposal 6 – Provide for computerised decision-making (computerised decision-making)

AMA supports this proposal in principle, as 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. However, any computerised decision-making systems and processes will need to be carefully and routinely validated to ensure the correct decisions are being made, and made consistently, and limit the need for additional human verification (which would undermine the efficiency gains offered by an automated decision-making system).

Proposal 7 – Improve the transparency of voluntary recalls (voluntary recalls)

AMA supports this proposal as it will improve awareness of recalls to the regulator and provide greater transparency to the end-users of agvet chemicals. In particular, AMA supports the requirement that a reason for the recall is also published, 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 for packaging issues.

AMA agrees that notifications should be restricted to recalls where there are issues related to the compliance of that product with the statutory criteria, or the distribution of an unregistered chemical product. Notification should not be required for voluntary recalls for reasons that are not associated with the statutory criteria.

There is a need for some flexibility to ensure multi-national companies can meet both local and global quality control and regulatory obligations. For this reason, AMA would support the alternative approach as described on page 30 of the consultation document, which requires that the approved form is provided to APVMA within two days of conducting a recall. For global companies, this form may require overseas approval before submission, which could take 24-48 hours to obtain. This would impose an undesirable delay on urgent recalls for safety or efficacy concerns. The registrant should always take primary responsibility for managing its products, and not become reliant on the regulator to issue recall notices. It is, however, appropriate that the regulator is kept fully informed of any such recalls, is notified within a reasonable timeframe, and can act as a public repository for recall notices.

The requirement to publish the entire approved form for the recall would act as a disincentive for companies to provide comprehensive information to APVMA. Some of the information on that form has no utility to the general public. Therefore, the preferred approach would be to publish a brief statement of the matters to which the recall notice relates, when necessary. Rapid publishing to the APVMA website is not that crucial, as relatively few people check the APVMA website on a daily basis for recalls.

There is also a need to establish clear decision points so that APVMA can determine when recalls are published, as there are different health, safety and trade risks associated with trade level versus consumer level recalls. For example, if a particular product has not left the warehouse, and therefore cannot and will not reach the consumer, a public notification should not be required. Recall notifications must remain focused on genuine issues which may impact the end users of that product.

AMA suggests that the proposed measures are commenced 6 months after Royal assent, which will allow sufficient time for APVMA to communicate the requirements to all registrants, and to establish the necessary internal systems and processes.

Proposal 8 – Require relevant information to be provided in relation to label approvals and variations (notification of new information)

AMA does not oppose this proposal, as it will align label approval and variations with existing requirements for active approvals and product registrations. However, AMA does not expect that this reform will deliver significant improvements in APVMA performance.

Proposal 9 – Standards for registered chemical product constituents (definition of registered chemical product)

AMA supports this proposal, as 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 further supports the proposed approach to consider veterinary chemical products differently to agricultural chemical products. 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.

Proposal 10 – Suspension of cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval (suspension or cancellation of approval or registration for provision of false or misleading information)

AMA supports this proposal. 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.

Proposal 11 – Addressing an inconsistency in label particulars (supply of registered chemical products with unapproved label)

AMA does not oppose this proposal but notes that this reform is addressing an existing inconsistency in regulatory requirements and is unlikely to deliver any improvement in APVMA regulatory performance.

Proposal 12 – Improving dealings with suspended approvals and registrations (variation of approval or registration during suspension)

AMA supports this proposal. Permitting an applicant to vary the relevant 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 allow the APVMA to remove a suspension and return a product to the market efficiently.

Proposal 13 – Address anomalies in matters that can be prescribed for statutory criteria (safety, efficacy, trade and labelling criteria)

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

Proposal 14 – Simplifying APVMA corporate reporting requirements (annual operational plans)

AMA supports this proposal. Removing duplication and inefficiencies in 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.

Proposal 15 – Align the 2014 legislation review with the overarching review of Agvet chemical legislation (other amendments)

AMA supports this proposal. AMA does not expect this reform to deliver efficiency reforms for the APVMA, however streamlining multiple, overlapping and duplicative reform processes will ensure the most efficient use for government and industry resources when reviewing current legislation.

Proposal 16 – Make minor and machinery changes to the Administration Act and Agvet Code (other amendments)

AMA does not oppose this proposal and notes that this merely removes redundant provisions.

Proposal 17 – Other Amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016 (other amendments)

AMA does not oppose this proposal. AMA notes that these provisions were previously proposed to be legislated in the Agriculture and Water Resources Legislation Amendment Bill.

In conclusion, AMA supports this Bill as a whole. We look forward to working with the government to deliver these reform measures and support the APVMA to deliver its legislated services efficiently and effectively. This will afford greater certainty to applicants in their dealings with the regulator and encourage them to bring new and innovative veterinary products to the market for the benefit of all Australian animals.