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18 February 2019

Agvet Chemical Regulation Reform Team

Department of Agriculture and Water Resources
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Canberra City ACT 2601

By email only: agvetreform@agriculture.gov.au

Dear Agvet Chemical Regulation Reform Team,

Re: Consultation on Agricultural and Veterinary Chemicals Legislation Amendment Regulations 2018

I am pleased to provide comments from Animal Medicines Australia (AMA) regarding the Agricultural and Veterinary Chemicals Legislation Amendment Regulations 2018 – *proposed changes to timeshift applications and other measures, and to support operational efficiency.*

AMA is the peak body representing the leading animal health companies in Australia. AMA member companies are 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.

AMA supports a risk-based regulatory environment that promotes sustainable animal health in Australia. AMA seeks to ensure that regulatory processes and outcomes adhere to COAG principles and guidelines for effective and efficient regulation, and that regulatory agencies adopt effective and appropriate risk management strategies to protect human, animal and environmental health.

We look forward to continuing engagement on these amendments. If we can provide additional information, please do not hesitate to contact me.

Yours Sincerely,

Ben Stapley

Executive Director

SUBMISSION TO THE
Consultation regarding the Agricultural and Veterinary
Chemicals Legislation Amendment Regulations 2018
Proposed changes to timeshift applications and other
measures, and to support operational efficiency

18 February 2019



**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.

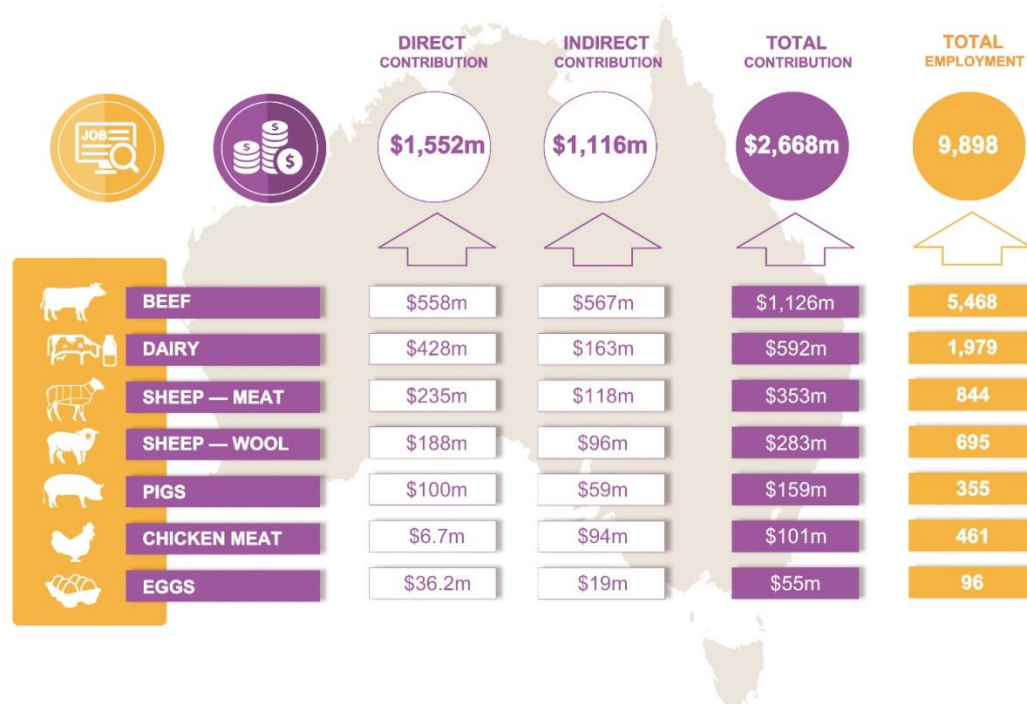
In the Australian livestock sector, AMA member company products increase farm productivity and deliver improved environmental, health, safety and animal welfare outcomes. These animal medicines also underpin the quality and safety of Australian livestock products for local consumption and export.

In the companion animal sector, veterinary medicines produced by AMA member companies facilitate longer and better quality partnerships between humans and their animals.

A recent report¹ commissioned by AMA confirms the essential role of animal medicines in supporting Australia's livestock industries. The analysis and report demonstrate that animal medicine products:

- contribute **\$2,668 million to the Australian economy;**
- create **9,898 full time jobs;**
- generate more than **\$578 million in wages;** and
- resulted in costs savings on an average grocery bill of **almost \$270 per annum.**

ESTIMATED TOTAL ECONOMIC AND EMPLOYMENT CONTRIBUTION ATTRIBUTABLE TO ANIMAL HEALTH PRODUCTS USE IN 2015-16



Note: Totals may not add due to rounding.
SOURCE: ACIL ALLEN CONSULTING ESTIMATES

Figure 1: The total economic and employment contribution attributable to animal medicines in 2015-16

¹ Acil Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries, 2015-16, June 2018

Proposal 1: Timeshift applications

In principle, AMA supports making timeshift arrangements available to Item 5, 10, 11 and 14 applications. This mechanism provides flexibility that is not available to other application types, and allows applicants to submit certain information while the assessment is underway. In particular, timeshift will allow the submission of additional time points in stability studies to support longer shelf life claims, which is a key issue for AMA members.

However, AMA would like to confirm the utility of timeshift for any appropriate data type, including efficacy and safety. For example, a number of efficacy studies may be required for some applications. Timeshift can allow the planned submission of one efficacy study at a later time than the primary efficacy and safety module with the agreement of APVMA. This may be useful where, for example, a particularly long study (such as duration of immunity) will be completed after the main body of an efficacy and safety submission is completed.

AMA also supports charging modular fees (as appropriate) for timeshift applications, rather than defaulting to the highest applicable fee. Greater availability of timeshift arrangements should not be deferred subject to a new Cost Recovery Impact Statement (CRIS). Fees for new timeshift applications should be able to be charged under the current PAA fee structure, at a tier appropriate to the level of complexity and effort required to develop that project plan.

AMA's support of this measure is subject to:

- the timeshift process allowing an applicant to supply *part* of a module at a later date during the assessment. If only *whole* modules can be timeshifted, no efficiency in assessing stability data is likely.
- agreement on a reasonable assessment timeframe for the timeshifted data. It would be counter-productive if APVMA required a substantial additional assessment time to assess one additional timepoint in a stability study where the earlier timepoints had been provided with the original submission.

However, AMA continues to have concerns about the appropriateness of timeshift as the primary mechanism to facilitate the provision of additional stability data. Timeshift applications involve a significant administrative burden for both the applicant and the regulator, which is not proportionate to the risk posed. AMA maintains its view that prescribing certain types of technical data that may be requested by APVMA without s159 notices (such as stability data) would provide a much simpler and more efficient mechanism. Further explanation is provided in our response to Proposal 12: Determining applications.

Proposal 2: Ministerial orders

AMA does not oppose this measure. However, this proposal is broad and the circumstances in which it could be utilised are not clear.

In principle, it is desirable to allow for ministerial orders to deal with matters in a more efficient and streamlined process than by making changes to the regulations. However, the process for regulation change is more transparent and consultative, and thus provides a level of oversight that could be missing from ministerial orders. AMA also has concerns that this measure may provide a mechanism for the Minister of the day to make important decisions without proper consideration or consultation with affected stakeholders.

AMA reserves its support of this measure pending more detail on the circumstances in which this measure could be utilised, including some limitations on its potential scope.

Proposal 3: Chemical product declarations

AMA supports this measure. Sheep branding substances pose a low risk and are appropriately controlled through other chemical laws in Australia without the need for additional specific controls under agvet legislation.

Proposal 4: Notifiable variations and prescribed variations

AMA supports this measure. It is desirable for the APVMA to have greater flexibility to define the scope of new notifiable and/or prescribed variations and be able to implement those changes more rapidly via legislative instrument (rather than via changes to Code Regulations).

Further, because notifiable and prescribed variations are administrative actions and do not require any technical assessment by APVMA, any fees that may be imposed should be standardised, regardless of what is being varied.

Proposal 5: Hormonal Growth Promotants

AMA does not oppose this measure. As major suppliers of hormonal growth promotants (HGP), AMA members support effective control over supply and use of these products to ensure that farmers have the option to use these products without compromising the ability of other producers to trade with non-HGP markets (such as the EU). An effective compliance regime is part of that control and ensures that APVMA has a broad range of actions available to discourage non-compliance.

AMA has some concerns that this measure will remove any discretion that the APVMA may have in this area, such as preventing APVMA from providing a person with a notification number (and therefore the ability to acquire HGPs for resale) if convicted of an Agvet (or similar) offence in the previous ten years. AMA would recommend that APVMA retains its discretion to provide a notification number. Retaining its discretion will also allow the APVMA to issue a notification number when a person has addressed the circumstances in which the Agvet offence was issued and enable a proportionate response to relatively minor offences. The offence could also have been of lesser relative importance in relation to the risk that resulted from the offence. AMA believes that APVMA remains the best placed to determine whether or not an applicant is a fit and proper person to hold a notification number.

Proposal 6: Section 88 exemption (allowing advertising)

AMA supports this measure, as it will allow the advertisement of animal medicines that play an important role in Australian animal health, but do not have a specific Australian registration and are used, legitimately, under the permit system.

However, it is unclear why the government has chosen to limit this provision to clauses 74 to 78 of the Agvet Code. If a permit is issued, then any factor under that permit should be allowed to be advertised. AMA recommends that registrants may advertise all approved permit uses of a product.

It may also be unclear from the permit itself, whether or not the permit has specifically triggered clauses 74 to 78. AMA members do not recall language used on permits that would clearly identify compliance with these clauses.

AMA further suggests that the criteria for exemption from Section 88 be expanded. For example, as in the situation presented on pg 25: "... a permit relating solely to supply of a chemical product in a container that does not have an approved label attached (section 80 of the Agvet Code) would not be covered by the proposed exemption. The government does not foresee the need to advertise substances or products solely related to any such permits." AMA contends that there *are* situations in which this exemption should apply. For example, if a registrant obtained a registration for a medication for a disease that was only intermittently present in Australia, the registrant may not create an Australia-specific label prior to the next outbreak occurring. The registrant may instead, apply for a permit to supply a product completely equivalent to the Australian registered product with the exception that the product was supplied with an overseas label to allow speed to market in an outbreak situation.

AMA has also identified an additional situation when a registrant cancels a registration and wishes to take advantage of provisions 45B and 45C of the Agvet Code, where the former registrant (and others within the supply chain) are taken to have a permit to continue to supply for 12 months after registration cancellation. Logically, the former registrant and others within the supply chain would want the ability to advertise the fact that they are selling out of that particular product. No formal permit is applied for that would clearly identify that clauses 74 to 78 had been triggered, yet in this circumstance, it would be reasonable to advertise.

Proposal 7: Restricted information

AMA recognises that the legislation needs to address an inconsistency in the use of the term "protected information" between the Code and its Regulations. However, it is unclear how this measure would affect APVMA approval of Item 5, 6 and 7 applications.

This proposal does not clarify whether it is intended that the information that remains 'protected information' because it was given as part of a reconsideration (i.e. the definition has not changed as part of this proposal) or in response to a request by APVMA, is also defined as 'restricted information'. AMA suggests that it should be.

This is also an issue with residue data. Where a registrant supplies residue data that leads to the changing of an MRL, a subsequent generic registrant does not need to rely on that protected/restricted information because they can simply cite the MRL. This is an anomaly and there should be no ability to rely on a changed MRL, where that MRL was changed based on data, and that data is still restricted.

Proposal 8: Assessment periods and fees (active approval as part of registration)

AMA supports this measure, as it will remove the need to provide separate applications when seeking registration of a new chemical product containing a new active constituent and with a new label.

Proposal 9: Consequential and other amendments

AMA supports this measure, as it removes provisions that are no longer necessary, corrects errors and deals with minor inconsistencies.

However, AMA notes that the reference to 'protected information' in Items 66, 67, 68, 73 and 74 seems to contradict Proposal 7 in this document, which suggests the use of 'restricted information'.

Proposal 10: Transitional provisions

AMA supports this proposal, as it will improve the implementation of changes proposed in the other measures.

Proposal 11: Voluntary recalls

AMA supports this measure in principle. AMA understands that currently, all recalls (voluntary or otherwise) need to be notified to APVMA. However, AMA agrees that there should be no requirement to publish a recall notice if that product has not been supplied to the retail level or purchased by users. Publication of a recall notice is unnecessary in this situation.

AMA agrees that APVMA requires a graduated suite of compliance options to address non-compliance in notifying APVMA of a voluntary recall related to the safety, trade, efficacy or labelling criteria, but AMA would like to better understand where APVMA has found their options in this area lacking in the past.

The Streamlining Regulation Bill (new section 106(1) of the Agvet Code) requires APVMA to be notified of a voluntary recall. New section 106(3) of the same bill states that the requirement to notify APVMA (section 106(2)) does *not* apply in circumstances outlined in the Regulations. However, there are no examples provided in this discussion document in relation to circumstances in which registrants would not have to inform APVMA. We look forward to working with the government to define the circumstances in which notification of a voluntary recall would not be required.

Proposal 12: Determining applications

AMA supports this measure as it will provide more flexibility for APVMA and applicants to deal with certain types of information provided while an application is under assessment, without triggering a compulsory extension to the assessment timeframe.

In particular AMA supports that Good Manufacturing Practice (GMP) certification for overseas sites of manufacture can be provided during an assessment without triggering an s159 notice and timeframe extension. At present, the APVMA approach to finalising an application requires the registrant to provide a current GMP certificate at the point of registration. When applications run over timeframe, it is possible that finalisation of the application may be further delayed while the applicant is required by APVMA to obtain another in-force GMP certificate, whereas if the application had not gone over timeframe, the original certificate provided at the time of application submission would have remained 'in-force'.

AMA suggests that a more reasonable and efficient approach would be for APVMA to assess the GMP certificate submitted with the original application and grant the registration with a condition that the requirements of the MLS for overseas sites are maintained by the registrant as required after registration.

AMA also agrees that applicants should also be able to provide further information under section 160A of the Agvet code without penalty.

AMA's perspective on the matter of regulations prescribing certain types of technical data that may be provided (pg 48):

This is a critical issue for AMA members, who have long been asking for a simple, pragmatic and efficient mechanism to allow the collection of real-time stability data whilst an application is under assessment, in order to obtain a suitable shelf life for that product. AMA acknowledges that the proposed changes to timeshift (as in Proposal 1) would provide an avenue for this to occur. However, AMA strongly maintains that the *most appropriate* mechanism to facilitate the provision of additional stability data would be through amendments to the Regulations to prescribe certain types of technical data that may be provided without s159 notice and extended timeframe.

The 2014 'shut the gate' amendments have resulted in delays to the commercialisation of products compared to the pre-2014 approach. For products such as vaccines, where the data are generally generated in real time, this has resulted in a delay of around a year to the time to approval with a commercially viable shelf life. For example, prior to 2014, the applicant may have submitted the application with 6 months stability data, and prior to registration, would have submitted the 18 month time point to support an 18 month shelf life.

Currently, the only options for registrants to obtain a commercially acceptable shelf-life are to delay the entire application until sufficient data are collected, or submit an additional variation application after the product has been registered. Both of these options delay the introduction of new products to the Australian market, to the detriment of registrants, vets, farmers and animal owners, relative to other geographies when other regulatory authorities permit submission of further stability data timepoints during the assessment period.

The Agvet Code does not preclude the regulations from prescribing certain types of technical data that may be provided. The Code clearly identifies that the types of technical data that could be provided on request during assessment would be enshrined in the Regulations – such changes to the Regulations would therefore not represent a return to the pre-2014 situation when additional field studies or new residues studies could be unexpectedly submitted by applicants, or negative assessments could be challenged with new data.

This amendment to the Regulations would provide an appropriate mechanism for applicants to continue real-time collection of stability data *whilst their application was under assessment*. The later timepoints in the stability trial/s can then be provided just prior to finalisation, on request from APVMA, to support the proposed shelf life.

It is important to emphasise that AMA is proposing a mechanism to allow the submission of additional timepoints in a stability study that was provided as part of the initial submission. AMA is not proposing that applications be submitted with no stability data, with the entire stability study to be submitted after the assessment commenced, nor is AMA proposing that applicants could provide an entirely new stability study, unrelated to the stability study provided with initial submission. Therefore, the APVMA will have the opportunity to assess the majority of the stability study including early time points, number of batches, test methods and their validation, storage conditions etc., prior to receipt of the final timepoint data.

The addition of a later timepoint to these existing studies would therefore only require minimal technical assessment to confirm that the longer shelf life would be supported. It would not require the assessment of a completely new study, as the only data we propose to be permitted would be to supplement the *existing* stability studies submitted in the initial application. This would, in fact, be a

more efficient process for APVMA, in comparison to commencing a new assessment for a new submission after approval of the initial application.

Further, applicants could be required to advise APVMA at the time of submission that the stability trials were ongoing and that the final stability data would be provided just prior to finalisation, so that the provision of additional data would be expected by the regulator.

AMA does not support the submission of incomplete applications, or the drip-feeding of data throughout an assessment. However, stability data and the resultant shelf life assessment, is a key consideration in the development and registration of a new product. AMA is seeking an efficient mechanism to allow for the submission of additional data, for an *existing* stability study, to be provided at a later time.

Whilst changes to timeshift (Proposal 1) would allow the provision of additional stability time points, the additional administrative burden for both applicant and regulator is not justified for what is, in effect, a simple process to agree that a later timepoint in an existing study will be provided prior to finalisation of the application. The need to have APVMA 'agree' to the later provision of stability time points also provides the option for APVMA to *not* agree. Further, the PAA required to support this agreement will be charged at the highest rates (usually reserved for the most complex timeshift arrangements), until a new CRIS is completed and implemented – in itself, a lengthy and complex process.

The provision of a simple, pragmatic and efficient mechanism to allow the submission of later timepoints in a stability study whilst an application is under assessment has been a key issue for AMA members for many years now. AMA continues to seek a solution that provides certainty for both APVMA and applicants, without imposing unjustified administrative costs on either party. The Agvet Code already provides an appropriate mechanism. AMA strongly supports amendments to the Regulations to prescribe certain types of technical information that may be provided during an assessment without the issue of s159 notices.

Proposal 13: Improving application quality

AMA does not support this proposal on three grounds:

1) Charging fees for s159 notices is inappropriate.

Charging fees for s159 notices assumes that the cause of a s159 is due to a deficiency within the application that can only be remedied by the applicant. This is frequently not the case. Applicants report receiving s159 notices seeking information and data that is already contained within an application. For example, s159 notices have been issued to AMA members when:

- the risk assessor has failed to notice information within the application dossier.
- the nature of a question asked by an external reviewer has not been understood by the risk assessor, who issues an s159 notice.
- the external assessor's report contains questions that can be answered by the risk assessor with data found in another part of the dossier, to which the external assessor had not been granted access. Instead of the risk assessor locating the answer, APVMA has issued an s159 notice to the registrant.
- different views on the science of a matter arise, and an s159 is issued to seek the registrant's response.

AMA notes that under this proposal, the APVMA would retain the ability to waive or remit fees. However, the remittance process for fees that may be inappropriately charged adds further complexity, time and uncertainty.

2) Charging for s159 notices provides a perverse incentive to the APVMA.

Issuing a s159 notice provides the APVMA with an additional evaluation time period (based on a statutory formula) with which to determine an application. Under this proposal, it would also provide an opportunity to collect additional fees in addition to the application fee already collected. This may encourage the regulator to more readily issue s159 notices (with the resulting additional fees and timeframe) rather than making a timely, risk-based decision.

AMA considers that the application fee should be sufficient to cover the entire costs of the assessment without additional fees being collected for s159 notices.

3) Identifying 'poor' or 'low quality' applications is impractical.

We reiterate our view that the issuing of an s159 by the APVMA is not necessarily due to a 'poor' or 'low quality' application being submitted, as the proposal seems to imply.

While there may be benefit to the APVMA and industry in better managing deficient applications, an effective system will require clear description of when an application contains incorrect and inadequate information, or is otherwise deficient.

Under the proposal, this approach would only apply after an application has passed preliminary assessment. There is a significant risk that subjective assessments of application quality by the APVMA could drive inconsistent outcomes for industry.

Without clear additional guidance, it is unclear how this approach could operate. In the absence of a clear definition of what constitutes a 'poor quality' or deficient application, there is a significant risk that any efficiency benefits associated with this proposal will be outweighed by an increased administrative burden on the regulator.

Encouraging APVMA to reach out to applicants to resolve minor issues (such as a missing page) is more efficient and recent experience of AMA members suggests that this approach is working well.

AMA's primary concern with this proposal is that the APVMA should focus on managing and evaluating good quality applications in a timely manner. It is counterproductive to encourage them to spend *more* time on poor quality applications, even if they charge a fee for that time. AMA would strongly prefer that APVMA did not expend scarce resources on applications that are clearly not of an acceptable standard and instead, focus resources on getting good quality applications finalised on time.

[Proposal 14: Annual returns reporting and false or misleading information](#)

AMA supports this measure, as it will provide APVMA with additional compliance options in relation to annual returns. However, AMA would be interested to understand where APVMA needs additional compliance options in relation to annual returns. AMA also supported the associated legislative measure in the Operational Efficiency Bill to simplify reporting requirements for annual returns and is keen to see that measure progressed through Parliament.

AMA notes that annual reporting can be further streamlined for some active ingredients. Whilst there may be utility in knowing the weight or volume of active pharmaceutical ingredients (when ingredients are measured in either of these parameters), there is no equivalent parameter to measure the active ingredients in vaccines. Biological active ingredients are measured in units such as TCID₅₀, which may vary between similar products, and the quantity of virus used in a vaccine has no practical meaning. AMA's view is that annual returns reporting for any active ingredient in which the quantity may have little practical relevance should be expressed in *doses* (eg: of vaccines) or removed from returns reporting.