12 March 2014
Agvet Chemicals Regulation Reform, M.6.137
Agricultural Productivity Division
Department of Agriculture
GPO Box 858
Canberra ACT 2601

By email: agvetreform@daff.gov.au

Dear Sir/Madam,

Re: Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2013

On behalf of Animal Medicines Australia, I provide the attached submission in response to the exposure draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2013.

Animal Medicines Australia supports regulatory reform that improves the efficiency of the Australian Pesticides and Veterinary Medicines Authority while maintaining its ability to ensure that chemicals supplied for use in Australia are safe and environmentally sustainable. Regrettably, the re-registration and re-approval provisions enacted during the life of the 43rd Parliament are inconsistent with the achievement of either of these important public policy aims. Accordingly, Animal Medicines Australia strongly supports their repeal, and commends the Government for moving swiftly to implement this important election commitment.

Animal Medicines Australia supports the Bill, but notes that further reforms are necessary to improve the efficiency and effectiveness of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). Some of those reforms are addressed in this submission; others appear in previous submissions made by this organisation under its previous name, the Animal Health Alliance (Australia) Ltd.

Please do not hesitate to contact me or Animal Medicines Australia’s Director of Regulatory Policy, Mr Michael Wright, if you should require any further information in relation to any aspect of this submission.

Yours Sincerely,

Duncan Bremner
Chief Executive Officer
SUBMISSION IN RESPONSE TO

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (REMOVING RE-APPROVAL AND RE-REGISTRATION) BILL 2013

EXPOSURE DRAFT

12 MARCH 2014
INTRODUCTION

Animal Medicines Australia is the peak industry body representing the animal health industry in Australia. Animal Medicines Australia 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 livestock sector, member company products are increasing agricultural yield while delivering improved environmental, health, safety and animal welfare outcomes. In the companion animal sector, veterinary medicines produced by member companies are enabling Australians to live longer, happier lives with the pets they love. Animal Medicines Australia is a member of the International Federation for Animal Health.

Animal Medicines Australia and its member companies promote the responsible use of all veterinary medicines. Responsible use entails using products as little as possible and as much as necessary, for the correct duration and in accordance with the APVMA-approved usage pattern. Animal Medicines Australia and its member companies participate in industry stewardship activities including drumMUSTER, ChemClear® and Agsafe Accreditation and Training.

Veterinary medicines are important tools for agricultural productivity. It is important that the veterinary chemical regulatory system is supportive of their continued availability and their responsible use. As Australian farmers compete for market share with overseas producers, access to innovative animal health technologies is absolutely critical to securing a competitive, profitable and sustainable future for Australian agriculture. While the need for new technologies increases, the expense associated with bringing new products onto the Australian market or extending existing products has also increased dramatically over the previous decade. In light of these developments, the reduction of the cost of regulation in a manner that maintains the APVMA’s ability to effectively manage risk is a public policy imperative.

1. Removal of re-registration and re-approval provisions

Animal Medicines Australia strongly supports the removal of re-registration and re-approval provisions from the Agvet Code. The re-registration and re-approval provisions are entirely duplicative of existing mechanisms for ensuring the ongoing safety and appropriateness of registered chemical products, but do not provide for the efficient allocation of resources according to the risk profile of any given chemical. If they were to commence operation, these provisions would divert resources away from APVMA’s targeted chemical review scheme, reducing the effectiveness of the APVMA. Further, they would significantly increase the cost of regulation, stifling Australians’ access to innovative veterinary medicines available elsewhere. It would dramatically increase the cost of regulatory activity and compliance, and would ultimately result in the diminution of the suite of veterinary chemicals available for Australian farmers and pet owners.

Additional transitional measures

Animal Medicines Australia notes with approval the proposed repeal of section 47A of the Agvet Code. The triggering of regulatory sanction based on decisions of regulators with a different appetite for risk is a simplistic, costly and ineffective approach to ensuring the safety of chemicals supplied for use in Australia. Animal Medicines Australia considers further regulations to be required as transitional measures to prevent perverse outcomes in the event the Amendment Bill does not receive Royal Assent prior to 1 July 2014. Specifically, Animal Medicines Australia calls for the list of foreign regulators appearing at Regulation 22D (which will currently commence operation on 1 July 2014) to be struck in its entirety prior to 1 July 2014. The prescription of foreign regulators for the purposes of section 47A of the Agvet Code is a condition precedent to the operation of the section. Absent repeal of regulation 22D, section 47A will impose statutory obligations on APVMA immediately it commences operation on 1 July 2014. Rather than create a need for remedial action after this date, Animal Medicines Australia considers it desirable to amend the Regulations prior to 1 July 2014 to “turn off” section 47A prior to its repeal from the Agvet Code.

2. Renewal Periods

Animal Medicines Australia supports the introduction of optional annual or multi-year registration renewal for veterinary medicine products. The introduction of multi-year registration renewal will represent a reduction in the burden of regulation currently felt by registrants, and will ensure APVMA efforts are not disproportionately spent on administrative aspects of the National Registration
Scheme. Animal Medicines Australia considers the optional model – where it is left to registrants to
determine the period of renewal that is best suited to the commercialisation of their product – to be an
effective mechanism to ensure that APVMA administrative functions are rationalized while providing
the flexibility that is required for a competitive, innovative market. If there are additional costs
associated with administering a more frequent renewal option, these costs should be borne by the
registrant availing themselves of this option.

3. Bolstering APVMA Compliance and Enforcement Powers

Public confidence in the safety of veterinary chemicals is an important factor in the success of the
veterinary medicines industry. Public confidence depends on the effectiveness of both pre-market and
post-market regulation. In relation to pre-market regulatory activities, the regulation of veterinary
chemicals by an independent scientific regulator means the public can be confident that chemicals
registered for use in Australia meet community expectations in relation to the health, safety and
environmental implications of their use. The proposal to strengthen the APVMA’s powers to obtain
information relating to the safety of veterinary chemicals will provide a further safeguard of public
confidence in the veterinary chemicals market. The strengthening of these powers will improve the
ability of the APVMA to ensure that the requirements of the Agvet Code are being complied with. In
this context, they represent an important advancement in the regulatory system.

4. Providing for simpler variations to approvals and registrations

It is desirable that the record of approved active constituents and the register of chemical products be
as accurate as possible. From time to time, approval holders and registrants need to alter the
particulars of an approved constituent or a registered product to reflect minor variations. The
mechanism for making such a variation should be designed in such a manner as to ensure that
registrants and approval holders are encouraged to avail themselves of it. As identified in the
consultation paper accompanying the exposure draft, the current processes for making such changes
are deficient in some respects. Animal Medicines Australia strongly supports moves to simplify
processes for making minor variations to the particulars of approvals and registrations. In this respect,
Animal Medicines Australia supports and echoes the comments made by CropLife Australia. What is
required to achieve greater simplicity in this area of regulation is a clearly defined set of
circumstances in which minor variations may be rendered more or less self-executing by way of
notification to APVMA. Animal Medicines Australia is encouraged by initial consultation on this matter
with the Department of Agriculture, and is eager to continue to work with the Department and APVMA
to make improvements in this area.

5. Removing requirement to make annual returns of technical grade active
constituents

Animal Medicines Australia supports the removal of the requirement to make annual returns of
technical grade active constituents. As noted in the consultation paper, this information is not required
for the administration of the NRS. As such, the administrative workload of APVMA could be reduced
by removing this requirement from the regulatory system.

6. Provision of information to APVMA via electronic means

Animal Medicines Australia supports the introduction of entirely electronic communication of
information and payment to APVMA. Provided the information technology infrastructure is sufficiently
robust to facilitate the transmission of vast quantities of data in a secure manner and that the format
of such data is easily complied with by applicants (for example standard pdf files), Animal Medicines
Australia views the move to an exclusively electronic system as desirable in the interests of a more
efficient, streamlined system.

In the course of APVMA Information Sessions in February and March, APVMA staff have discussed
the possibility of allowing hard copies of documents to be used to communicate information in
exceptional circumstances. If there is a genuine need to provide for the use of hard copy in
exceptional circumstances, Animal Medicines Australia would not oppose such a provision. However,
like CropLife, Animal Medicines Australia considers it appropriate that if the use of hard copy

increases the administrative cost to the APVMA, the cost should be recovered from the applicant in question.

7. Provision of information for fee

Animal Medicines Australia believes applicants should be able to request information they themselves have provided to APVMA without the need to go through an expensive and time-consuming FOI process. Accordingly, Animal Medicines Australia strongly supports the introduction of a user-pays system for eligible parties to obtain information from APVMA which would, under the existing system, trigger the operation of FOI provisions. The introduction of such a system would encourage parties to keep adequate records of information transmitted to APVMA, and where circumstances arose requiring a registrant or approval holder to seek information, the cost of processing the request would be directly recovered from the applicant in question. Animal Medicines Australia welcomes this measure, which will put a halt to APVMA resources being diverted from core business to administrative processes that ought to be undertaken – or, at the very least, paid for – by registrants and approval holders.

8. Other amendments

Animal Medicines Australia supports the amendments contained in the exposure draft. There are a number of issues that the provisions of the Bill do not currently address, and Animal Medicines Australia recommends a number of further reforms be implemented to improve the veterinary medicines regulatory system. These are:

(i) Pre-application assistance

Animal Medicines Australia is supportive of the provision of pre-application assistance if an applicant considers such assistance to be required. However, Animal Medicines Australia’s support for this initiative is subject to the cost recovery arrangements adopted for this particular activity. As noted in previous submissions as part of the Better Regulations reform process, Animal Medicines Australia member companies employ professional regulatory affairs teams who are more than capable – and should have the flexibility – to decide on a case by case basis whether to avail themselves of the pre-application assistance services being offered by APVMA. Where an applicant considers that pre-application assistance is necessary or desirable, the applicant should have to pay for the actual cost associated with the provision of that service.

The clarity and completeness of APVMA regulatory guidelines and associated instruments will have an important influence on the extent to which applicants will require pre-application assistance. It is important that the availability of pre-application assistance does not stifle efforts to achieve clarity in this area. At present, the legislative instrument setting out the information that must accompany an application on or after 1 July 2014 has not been made publicly available, so to some extent industry is limited in its ability to make specific comments going to the degree to which the new (post-1 July 2014) guidelines will be capable of being relied on in the case of routine applications. It is hoped that the publicly available guidelines will be sufficiently clear to allow pre-application assistance to be limited to a class of applications dealing with innovative – and therefore, more complex – applications in relation to which pre-project assistance will yield dividends in terms of efficiency.

(ii) Application timeframes

Application timeframes are an important mechanism for delivering predictability and certainty to the veterinary chemicals regulatory system. It is important that they are adhered to in order for applicants to plan and execute the commercialisation of their products. When APVMA is unable to meet the timeframes for the assessment of an application for approval of an active constituent or registration of a chemical product, the delay has the potential to cause immense cost to applicants who may forgo the opportunity to bring their product to market for an entire season, if not longer. Animal Medicines Australia commends the work being done internally by APVMA to improve its business processes to ensure its activities are as efficient as possible. It is hoped that this work will increase the percentage of applications determined within time. Whether or not this is the case, it is prudent for the Agvet Code to be sufficiently flexible to ensure that if an application is not determined within time, an applicant is not further penalised.
It is likely that the greatest potential for delay in the assessment of an application will occur where the application raises questions of a unique character. This is most commonly the case where the application is for either:

(a) approval of an active constituent that is not a previously approved active constituent; or

(b) registration of a chemical product containing an active constituent that is not an active constituent contained in any other registered chemical product.

Animal Medicines Australia notes that an application answering to the above description may meet the definition of “timeshift application” for the purposes of the Agvet Code Regulations if mutual agreement to this effect is reached between an applicant and APVMA. 1 Timeshift applications are treated differently insofar as their assessment periods are provided for in project plans agreed between the APVMA and the applicant. 2 Subregulation 8AG(2) provides that an applicant and the APVMA may agree to vary a timeframe or assessment period set out in the project plan, and may do so at any time. Animal Medicines Australia supports this arrangement, as it acknowledges the increased potential for novel issues to arise in relation to such applications.

Notwithstanding the comfort Animal Medicines Australia finds in the timeshift application arrangements, not all complex applications are timeshift applications. It is not inconceivable that applications that are not timeshift applications may nevertheless be the subject of delay. In this context, it is important to note that external agencies engaged by APVMA to perform evaluations might contribute to delay in the making of a determination by APVMA. The potential for this to occur is increased due to the lack of competitive pressure on external agencies to ensure that the services they provide are timely and cost-effective. In the event that a delay does occur, and an application is not determined within the extended maximum assessment period, it is important that the regulatory system is not so inflexible as to shift the consequences of delayed assessment onto a faultless applicant.

In this context, Animal Medicines Australia acknowledges that section 165(3) of the Agvet Code provides an option for an applicant to request APVMA to refuse their application if it has not been determined in accordance with a statutory timeframe. Such a request is made by notification in writing to APVMA. If such a notification is given, the Agvet Code applies as if the APVMA had made a decision to refuse the application. Internal review is by-passed by virtue of section 165(5)(b), facilitating recourse to the Administrative Appeals Tribunal.

Appeal to the Administrative Appeals Tribunal is not a particularly attractive remedial mechanism for applicants who experience delay through no fault of their own. As it is conceivable that applications that do not fall within the definition of timeshift applications may in some circumstances remain undetermined at the expiration of the extended maximum assessment period, it is important that the regulatory system should provide for the further extension of the extended maximum assessment period to safeguard the interests of faultless applicants.

(iii) Risk and Hazard

Animal Medicines Australia shares the concerns expressed by CropLife Australia in relation to the confusion between the concepts of hazard and risk evinced by section 5A of the Agvet Code. Risk based registration systems offer product users appropriate management advice relating to the most important hazards associated with the product through clear label instructions. Animal Medicines Australia continues to support risk management as the primary tool for regulating veterinary active constituents and their associated products in Australia. Animal Medicines Australia does not support approaches to regulation of veterinary chemical products that focus solely on the hazards associated with the active constituents in the products. In previous submissions during the Better Regulation Reform process, Animal Medicines Australia (as Animal Health Alliance (Australia) Ltd) expressed its concern that elements of hazard control were appearing in the Agvet Code and associated legislative instruments. The concern relates to the intermingling of elements of hazard control with risk control statements. Initially, this appeared to be limited to calculation of timeframes for re-approval and re-

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1 By virtue of the definition of “timeshift application” appearing at subregulation 3(1) of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Cth), an application is not a timeshift application if the applicant and APVMA have not agreed to it being treated as such.

2 See definition of “timeshift application” appearing at subregulation 3(1) of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Cth).
registration. Animal Medicines Australia is concerned that the Amending Bill does not currently seek to completely remove references to hazard control from the Agvet Code.

9. Further reforms

There are a number of further reforms that would, if implemented, increase the efficiency and effectiveness of the APVMA. These include:

(i) **Provide for greater recognition of assessments and decisions of OECD regulators on identical products**

One of the greatest barriers to the introduction of innovative products to the Australian market is the practice of APVMA repeating assessments of efficacy and safety data on products that have already been comprehensively assessed by similar OECD regulatory authorities. The requirement for applicants to generate data to facilitate this regulatory duplication is costly and time consuming, and represents an enormous disincentive for companies to commercialise products in Australia. This has broader implications for Australia’s agricultural productivity, because it is often the case that Australia’s competitors already have access to a cheaper, safer and more efficient product. It is also highly unsatisfactory, from an efficiency perspective, for highly skilled regulators to be devoting time to carry out assessment of information which should lead to the same decision as has previously been made by a similar OECD regulator. APVMA will want to assess data where there are local considerations which may result in a different assessment outcome, but this is very unlikely to be the case for some parts of an application, for example toxicology and metabolism.

(ii) **Disband the APVMA Advisory Board**

Animal Medicines Australia considers the disbandment of the APVMA Advisory Board to be in the interests of streamlining the operations of APVMA. The APVMA employs a senior executive team with responsibility for the strategic direction of the authority, and industry and the broader community have various avenues for participating in consultation with APVMA. The resources necessary to provide secretariat support for the Advisory Board would be better spent on APVMA regulatory activity.

**Conclusion**

Animal Medicines Australia supports the enactment of the Amending Bill as an important step towards securing an efficient and effective regulatory system for veterinary chemicals in Australia. It commends the Government for acting swiftly to implement this key election commitment.

If enacted, the Bill will secure a more efficient regulatory system while maintaining the APVMA’s ability to ensure that chemicals supplied for use in Australia are safe and sustainable. Accordingly, the Bill should be vigorously supported.