Animal Medicines Australia

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18 April 2014

Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
Canberra ACT 2600

By email: rrat.sen@aph.gov.au

Dear Sir/Madam,

Re: Inquiry into the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014*

On behalf of Animal Medicines Australia, I provide the attached submission for the purposes of the Committee's Inquiry into the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014*.

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.

The re-approval and re-registration provisions enacted during the life of the previous Parliament are inconsistent with the achievement of either of these important public policy aims. Superimposing re-approval and re-registration on the APVMA's existing chemical review program risks undermining the effectiveness of that program by diverting resources away from targeted, risk-based chemical review. Such an outcome would reduce public confidence in the regulatory system while increasing the regulatory burden imposed on innovators of new veterinary medicinal technologies. Environmental, human and animal health interests are best served by the repeal of the re-approval and re-registration provisions prior to their commencement on 1 July 2014.

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 TO THE SENATE STANDING COMMITTEES ON RURAL AND REGIONAL AFFAIRS AND TRANSPORT

INQUIRY INTO THE *AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (REMOVING RE-APPROVAL AND RE-REGISTRATION) BILL 2014*

18 APRIL 2014

Animal Medicines Australia

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 ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training.

Veterinary medicines are important tools for agricultural productivity. They are also essential for the health and wellbeing of Australian pets. 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 or even strengthens the APVMA's ability to effectively manage risk is a public policy imperative.

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

Accordingly, Animal Medicines Australia strongly supports the removal of re-approval and re-registration provisions from the Agvet Code prior to their proposed commencement date of 1 July 2014.

Animal Medicines Australia is concerned that the commencement of a mandatory, time-based re-approval and re-registration scheme would risk diminishing the APVMA's ability to ensure that chemicals registered for supply in Australia continue to be safe for humans, animals and the environment.

The APVMA's reconsideration (chemical review) program allows for the allocation of resources based on the risk profile of any given chemistry, ensuring that finite resources are allocated in a targeted manner. It makes little sense for these resources to be spread thinly between all products on the Register, regardless of their risk profile. Yet this is precisely the course of action that is prescribed by the re-approval and re-registration scheme. Re-approval and re-registration would dramatically increase the cost of regulatory activity and compliance, and would ultimately result in the diminution of the suite of veterinary medicinal products available for Australian farmers and pet owners.

The submission of CropLife Australia outlines in more detail the argument for removing the re-approval and re-registration provisions. Animal Medicines Australia echoes and supports CropLife's submission.

2. Removing Foreign Regulator Trigger

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.

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. 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.

5. 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 Explanatory Memorandum, 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.

6. 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.

7. 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.

8. 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.

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.

The proposed repeal of re-approval and re-registration provisions prior to their coming into effect on 1 July 2014 must be viewed in the context of steps that have been taken to improve the timeliness of the APVMA's existing chemical review scheme. Those steps were taken in response to legitimate criticism over the timeliness of chemical review. It would come as a retrograde step if a program that allows for the prioritisation of reviews according to risk profile was debilitated due to the superimposition of an arbitrary re-registration and re-approval scheme. Human health, animal health, and environmental sustainability are all best served by the repeal of the re-approval and re-registration provisions.

The Bill will improve the APVMA's compliance and enforcement powers, bolstering its capacity to ensure that the provisions of the Agvet Code are complied with. These provisions will further add to public confidence in the system of agvet chemical regulation in Australia.

Amendments aimed at streamlining variations to particulars of registrations or approvals will improve the accuracy of the record and the register, and will reduce regulatory burden, allowing APVMA resources to be focussed on core functions.

Animal Medicines Australia considers the provisions of the Bill to be appropriately adapted to securing a more efficient regulatory system while strengthening the APVMA's ability to ensure that chemicals supplied for use in Australia are safe and sustainable. Accordingly, the Bill should be vigorously supported.