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Lodged online: via the Citizen Space Consultation Hub https://consultations.health.gov.au/health-systems-policy-division/genetechreview2017/consultation/intro/

Dear Gene Technology Scheme Committee,

Re: Submission to the Review of the National Gene Technology Scheme 2017

On behalf of Animal Medicines Australia, I write to provide our submission to the 2017 Review of the Gene Technology Scheme.

Animal Medicines Australia is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. We have a strong interest in ensuring that new veterinary medicines can be registered for use in Australia for the benefit of animal health and welfare, agricultural productivity and public health.

To date, interactions between AMA members and the Regulator have primarily concerned animal vaccines. However, genetic modification (GM) and gene technologies (GT) are becoming increasingly important in veterinary medicine, and in the future, our members hope to register innovative new veterinary medicines developed using GT for use in Australia, including antivenoms, vector vaccines, antivirals, immunoglobulins and monoclonal antibodies.

Yours sincerely,

Ben Stapley

Executive Director

SUBMISSION TO THE

Review of the National Gene Technology Scheme 2017

15 September 2017

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.

To date, interactions between AMA members and the Regulator have primarily concerned animal vaccines. However, genetic modification (GM) and gene technologies (GT) are becoming increasingly important in veterinary medicine, just as they are in human medicine. In the future, innovative new veterinary medicines developed using GT may be registered for use in Australia, such as antisera, vector vaccines, antivirals, immunoglobulins and monoclonal antibodies.

AMA supports the need for regulation of gene technologies (GT) and genetically modified organisms (GMOs) that reflects a true level of risk and is based on reliable scientific evidence. We support a regulatory approach that allows new technologies to be used to improve animal health and welfare, and protect public health, while preventing unacceptable risks to the health of animals, humans or the environment.

The discipline of GT and GMOs has advanced rapidly since the *Gene Technology Act (2000)* was created, such that the Act itself now requires significant updating to ensure that it remains fit for purpose. In particular, the definitions of GT and GMO in the Act, which underpin every aspect of the associated legislation, should be updated promptly to reflect current knowledge and understanding.

Our priority is to maintain a functional and robust, scientifically-based GT/GMO regulatory system. We wish to maintain and promote positive and productive relationships between the Regulator and our members, so that the Regulator can continue to meet all of its legislated timeframes.

Our suggestions for future improvements to the Scheme are to:

1. Remove the duplication of regulation between APVMA and OGTR, and clarify the role of each Regulator in the assessment of new veterinary medicines
2. Promote a regulatory approach that objectively assesses the potential risks associated with the approval of a new GT or GMO
3. Promote the harmonisation of regulatory standards with those used by recognised overseas regulators to support the registration of important new veterinary medicines for Australian animals, especially for products that have an established history of safe and efficacious use
4. Increase the flexibility of the Regulator to accommodate the rapid rate of technological change in GT

In response to the specific Terms of Reference of the 2017 Review of the Gene Technology Scheme:

TOR 1. Current developments and techniques, as well as extensions and advancements in gene technology to ensure the Scheme can accommodate continued technological development.

AMA supports a balanced approach to the classification of what is and is not considered to be GT/GMO. It is significantly more expensive and time-consuming to register a new product if it is determined to be GM, and the present regulatory system is a strong disincentive for companies to bring innovative new veterinary medicines to the Australian market.

We would like to see that the Regulator is given greater discretion to amend Schedules 1 and 1A, which define genetically modified organisms (Schedule 1) and gene technologies (Schedule 1A) to be assessed by the OGTR. The technology in this area is changing rapidly and the Regulator should be able to make legally binding decisions on what is and is not assessed, without requiring legislative change.

At present, the identification of a GT/GMO is based on the *process* used to develop that product. Thus, if GT was used at any point in development, then that product is classed as GM – even if the end product contains no actual genetic material. The use of a process-based trigger for GM consideration is not scientifically justified and has a strong inhibitory effect on the development and commercialisation of potentially beneficial animal medicines in the future.

In contrast, a *product*-based classification offers a more balanced approach to risk assessment that is commensurate with the actual level of risk. Many GM products are genetically identical to, and thus indistinguishable from, the same products developed using 'traditional' ('non-GM') methods. For example, GM has traditionally been achieved through the selective breeding of livestock through successive generations to promote certain genetic traits, such as polled (hornless) cattle or particular fleece types in sheep. Gene editing techniques achieve the same end point (i.e. a cow that lacks horn buds), but with a much greater level of precision and control by targeting only the specific genes associated with the desired trait.

AMA also supports increasing the flexibility of the OGTR and APVMA to assess new GT/GMOs in veterinary medicine by facilitating access to, and harmonising registration requirements with, international expertise and regulatory agencies, especially those with an established history in the registration and safe use of GM pharmaceuticals. For example, the global veterinary vaccine market has grown dramatically in the last decade with the use of Recombinant Vaccine technology to develop many new vaccines that protect against commercially devastating diseases in livestock (especially in the poultry and porcine industries), and serious illnesses in companion animals. At present, only a limited number of these vaccines are available to Australian farmers and pet owners, despite their history of safe use overseas.

Increased flexibility for the OGTR to assess new gene technologies, such as recombinant vaccines, will offer substantial benefits for Australian farmers and pet owners, assist in maintaining Australia's agricultural advantage in global trade markets, support healthier animal and human populations, and support optimal health and welfare for all Australian animals. It will also facilitate the alignment of our animal production systems with industry sustainability goals through greater productivity, improved animal welfare through lower disease incidence, lower human health risks from animal-to-human-transmissible diseases, and the production of safer and more reliable food products from animals.

TOR 2. Existing and potential mechanisms to facilitate an agile and effective Scheme, which will ensure continued protection of health and safety of people and the environment.

AMA supports changes that will reduce the level of regulatory duplication between APVMA and the OGTR, and that clarify the responsibilities of each Regulator with respect to veterinary medicines. The registration requirements for both Regulators are comparable in terms of the data requirements and risk assessments, but the format of each application differs, so two separate application dossiers must be generated by the registrant for the same product. The need to obtain two separate registrations for a single product does not provide a greater level of risk assessment or risk management than a single APVMA license confers. The requirement for duplicate registrations from separate Regulators also imposes significant financial and time costs on registrants, and deters registrants from bringing new veterinary medicines to the Australian market.

AMA recommends that the APVMA should assume sole responsibility for the registration and compliance of *all* veterinary medicines, including GM veterinary medicines. The assessment of such products should be based on clear international guidelines, such as VICH. The regulatory clarity provided by having a single regulator for all veterinary medicines will significantly reduce the cost and time needed to bring a new veterinary medicine to the Australian market for the benefit of both livestock and pets, with no reduction in the rigour of risk assessment.

AMA would also like to see a risk assessment framework that distinguishes between GM products for companion animals and those for food-production species. Companion animals do not enter the food chain, so GM medicines used in these animals pose much lower risks to human health than products used in livestock. The risk assessment process should reflect this difference in the actual level of risk associated with the use of particular products.

There are currently numerous GM vaccines for companion animals with a long history of safe and efficacious use overseas, but that are not registered for use in Australian pets. Vaccines are a vital tool to protect animal health and reduce the incidence of diseases that are often treated with antibiotics. Reductions in disease incidence through vaccination will reduce the need for antibiotic use in animals, and thereby reduce the risks associated with antimicrobial resistance (AMR) for both animals and humans. The spread of resistant microorganisms is a particular concern with companion animals due to our shared living spaces and prolonged close contact. Improvements in animal health associated with vaccination and the responsible use of antibiotics could have substantial public health benefits.

TOR 3. The appropriate legislative arrangements to meet the needs of the Scheme, now and into the future, including the Gene Technology Agreement.

AMA supports actions that will increase harmonisation of Australian regulations with the standards and processes of equivalent regulators overseas. Internationally-developed guidelines for the assessment of veterinary medicines, such as VICH, provide a universal, science-based framework for regulation. Further, the definitions of a regulated article or technique are not consistent between regulatory agencies, adding a further barrier to the introduction of new medicines to Australia.

In addition, AMA supports the acceptance of international regulatory assessments with respect to human health. The health risks of a new product (for a given usage pattern) would be equivalent in any human population, regardless of their geographic location – there is nothing intrinsically different about Australian users. This would reduce assessment timeframes and data requirements for products that are already well characterised and have a history of safe use elsewhere.

However, we recognise that the Australian landscape and native species are unique, and therefore specific risk assessments for Australia as a receiving environment, with different target and non-target organisms, would be appropriate.

AMA strongly supports actions to strengthen and streamline the emergency mechanisms within the Act to make GM veterinary medicines available quickly in an emergency or exceptional circumstance. This mechanism was used during the 2007 outbreak of Equine Influenza (EI). There was no vaccine for EI registered for use in Australia at the time. An emergency dealing determination under the *Gene Technology Act 2000,* together with permits issued under the *Quarantine Act 1908 (Cwlth)* and by the APVMA, allowed a vaccine used overseas to be rapidly approved and imported. The vaccine played a critical role in the subsequent control of the outbreak and eventual re-acquisition of Australia's valuable EI-free status. A mechanism to facilitate access to critical veterinary medicines in an emergency or exceptional circumstance is critical to protect human and animal health, and to minimise potentially catastrophic commercial costs to key animal industries.

TOR 4. Funding arrangements to ensure sustainable funding levels and mechanisms are aligned with the level and depth of activity to support the Scheme.

AMA supports a level of cost recovery that is appropriate to support the regulation of veterinary medicines, including GM medicines. However, this must be balanced by the provision of balanced, scientifically sound, and efficient regulatory assessments that do not create unreasonable barriers for innovative and effective products to benefit Australian farmers and pet owners. It is inappropriate for industry funds to be used to subsidise an inefficient or unreasonably risk-averse regulator.