Animal Medicines Australia

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

10 March 2017

Senate Finance and Public Administration Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

By email only

Dear Sir/Madam

Re: Animal Medicines Australia submission on *The operation, effectiveness, and consequences of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*

On behalf of Animal Medicines Australia, please accept our submission to the Senate's inquiry into the operation, effectiveness, and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*.

As the national association for veterinary medicine approval holders, Animal Medicines Australia (AMA) has a strong interest in ensuring that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is able to maintain its ability to administer the Agricultural and Veterinary Chemicals Code in an effective and efficient manner. Our submission outlines several risks resulting from the Government's decision to relocate this agency from Canberra to Armidale, and measures that should be urgently taken to mitigate these risks.

Generally, AMA does not oppose policies to position government agencies to regional and rural locations. However, the APVMA has some specific features and functions that will result in net costs to our members as well as diminishing the productivity and profitability of Australian farmers. These issues will need to be addressed to avoid a serious and significant decline in agency performance that will not only impact on veterinary medicine approval holders, but also farmers, pet owners and others individuals reliant on timely access to the latest innovations in veterinary medicine.

Should you have any questions in relation to the content of this submission, please contact me.

Yours Sincerely

Ben Stapley
Executive Director

AMA SUBMISSION TO THE SENATE FINANCE AND PUBLIC ADMINISTRATION COMMITTEE ON

The operation, effectiveness, and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*

10 March 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 local arms of global 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.

Our members engage with the APVMA regularly and have a strong interest in ensuring that the regulator is able to deliver timely, predictable and efficient veterinary medicine approvals. As such, understanding the impact of the APVMA's relocation on the regulator's functions and performance is critical for the business and strategic planning of our members.

AMA is very concerned that the relocation of the APVMA will have a serious, negative impact on the APVMA's performance. Recent weeks and months have confirmed that key, significant risks to APVMA performance are now occurring. Significant actions need to occur now to mitigate these risks.

In summary:

- The Government Policy Order relocating the APVMA has resulted in uncertainty and insecurity for APVMA employees,
- This uncertainty has had a serious impact on APVMA's ability to attract and retain suitable staff,
- Regulatory scientists are highly specialised and in high demand both in Australia and globally. Loss of these staff fundamentally undermines APVMA assessment and approval performance,
- This puts the regulatory scheme for veterinary medicines at risk; and
- Flow on impacts for livestock and animal production industries reliant on access to the latest veterinary medicine innovations will be significant.

Relocation to Armidale will pose some additional challenges and costs for APVMA to provide technical advice to inform Government policy functions. Costs will also be borne by both APVMA and industry applicants when engaging with a regionally located regulator. A less accessible regulator may ultimately result in a regulator that is less accountable to Government and industry stakeholders.

For these reasons, AMA does not support the relocation of the APVMA. Relocation will negatively impact on the capability of the APVMA to facilitate introduction of the latest veterinary medicine innovations.

A. IMPACT OF ORDER ON GOVERNANCE OF COMMONWEALTH CORPORATE ENTITIES

AMA places significant value on APVMA being highly accountable for its activities. This includes ensuring that the regulator remains free from improper external influences when deciding whether to grant a product approval. An accountable, independent regulator that makes timely, science-based assessment decisions is important for several reasons. These include:

- Ensuring that costs recovered from industry to administer the agvet code are managed responsibly, and with the lowest pre-market barrier possible;
- Ensuring that appropriate improvements in assessment processes are vigorously pursued; and
- Ensuring that decisions made by the regulator are based on genuine assessments of risk.

Critically, an independent regulator ensures that applicants proposing new and innovative products receive a balanced and fair assessment of their application that is not influenced by irrelevant external political considerations. AMA is concerned that the policy order directs the APVMA to undertake activities that undermine the efficient management of its operations without delivering any benefit in structure, operation or service delivery. As a result, APVMA performance has been severely undermined.

AMA's view is that the CEO of the APVMA is responsible for deciding, within the context of the existing legislative and regulatory framework, how to ensure that the purposes of the Agvet Code can be best delivered. Indeed, this is consistent with the CEO's duties under the Public Governance, Performance and Accountability Act 2013 (PGPA Act) for the CEO to administer funds efficiently. These general duties expressed under section 15 of the PGPA:

15 Duty to govern the Commonwealth entity

(1) The accountable authority of a Commonwealth entity must govern the entity in a way that:

(a) promotes the proper use and management of public resources for which the authority is responsible; and

(b) promotes the achievement of the purposes of the entity; and

(c) promotes the financial sustainability of the entity.

Note: Section 21 (which is about the application of government policy) affects how this duty applies to accountable authorities of non-corporate Commonwealth entities.

(2) In making decisions for the purposes of subsection (1), the accountable authority must take into account the effect of those decisions on public resources generally.

As highlighted by the *Cost Benefit and Risk Analysis of the Potential Relocation of the APVMA*[1], relocation creates several significant risks that are very likely to result in significant disruption to APVMA operations to the detriment of AMA members, farmers and others that rely on the latest veterinary medicine innovations. These key risks include:

- Risk 1: The APVMA is unable to effectively relocate or recruit and replace key APVMA executive, management and technical assessment staff within the first two years.
- Risk 2: During transition and in the short term, the APVMA is unable to sustain its rate of effort for registration of new agricultural and veterinary chemical products.
- Risk 3: The APVMA is unable to maintain and grow its capability in the medium term.

Noting these key risks associated with relocation, issuing the order undermines the APVMA CEO's duty under 15(1)(a) and (b).

[1] http://www.agriculture.gov.au/SiteCollectionDocuments/apvma-cost-benefit-analysis.pdf

B. THE POLICY OF RELOCATING CORPORATE COMMONWEALTH ENTITIES WITH AGRICULTURAL POLICY OR REGULATORY RESPONSIBILITIES,

In principle, AMA believes that Commonwealth entities, especially those with regulatory responsibilities, should be located where they may be most effective and efficient. That is in considering where it may be best located, a regulator should consider (among other things):

- Its human resources, financial and infrastructure requirements,
- Its accountability responsibilities, and
- Its need to engage with key stakeholder groups.

AMA therefore would not oppose relocation if it was consistent with a sober assessment of the functions of the agency and an independent assessment of how those functions could be most efficiently and effectively delivered. On these criteria, relocation of the APVMA is unlikely to deliver a superior regulatory outcome. AMA makes this assessment as:

- APVMA's human resources are currently being severely and rapidly depleted. This is already having a deleterious impact on the APVMA's capacity to deliver timely approvals;
- APVMA is appropriately accountable to the Commonwealth Government. Reducing the APVMA's accessibility by locating it in a regional location will not enhance this accountability.
- In addition to Government, APVMA's key stakeholders include its regulated community – approval holders for agricultural chemicals and veterinary medicines. Overwhelmingly, these companies are located in either Sydney or Melbourne. Moving the regulator to a more remote location (compared to Canberra) is highly unlikely to result in superior engagement with its key stakeholders.

AMA accepts that eventually the APVMA may ultimately effectively operate from Armidale. However, the government's relocation policy must result in a regulator that offers an improvement over the status quo. For some other agencies that have been relocated (such as the Grains Research Development Corporation) a regional location may be most appropriate. In the APVMA's case, adoption of a relocation policy:

- Is highly unlikely to result in a superior performing regulator; and
- Will incur significant and enduring costs to applicants and farmers during the transition from Canberra to Armidale, in particular due to the opportunity cost of delays to registration and availability of new innovative products.

On this basis AMA does not support relocation of the APVMA.

C. THE POLICY'S EFFECT ON THE ABILITY OF AFFECTED ENTITIES TO PERFORM THEIR FUNCTIONS

AMA's views on the ability of the APVMA to be able to continue to perform its functions in Armidale assume that the agency will maintain its current regulatory functions and business processes.

AMA holds serious concerns that the APVMA will not be able to continue to effectively administer the Agvet Code. The reasons for this have been well canvassed publicly and relate to the ability of the APVMA to attract and retain highly qualified regulatory scientists and assessors.

Appropriately qualified persons capable of using sound judgement to fairly assess agvet product applications remain in high demand in both Australia and overseas. All evidence to date indicates that the APVMA should be preparing for a delivery model with fewer regulatory assessment staff.

Over the last eight months since the election, nearly 25% of APVMA staff have departed the agency. Of most concern, APVMA has lost 20 of its 100 regulatory scientists, including several senior regulatory scientists with more than 20-years experience. On average, departing regulatory scientists have had approximately 5-years experience. Some key assessment sections are operating with half the number of assessors required. Legislated assessment timeframes are not being met.

AMA expects that the APVMA will continue to lose essential employees, that it will continue to struggle to fill vacancies and therefore, it will not be able to adequately deliver assessments in a timely manner.

Declining resources will increasingly require the APVMA to prioritise its functions. AMA expects that the APVMA will be required to dedicate an increasing proportion of remaining resources towards application assessment. This will mean that other desirable functions may not occur. Other functions of the APVMA that will be negatively impacted will include:

- Development of guidelines, risk frameworks and assistance for potential applicants,
- Support for regulatory reform initiatives to streamline and reduce regulatory burdens,
- Progress on existing and future priority chemical reviews.

During the October-December 2016 quarter, APVMA reported a significant decline in pesticide approval performance. As the agency continues to lose staff, AMA expects to observe continuing declines. Some areas of APVMA assessment will have a disproportional impact on assessment performance. For example, all products used in food crops or in food producing species will require a residues assessment. If the APVMA is unable to adequately maintain assessors in this area, the impact on assessment performance will deteriorate.

D. CONCLUSION

AMA holds deep concerns that the Government Policy Order to relocate the APVMA is undermining the capacity of the APVMA to administer the regulatory scheme for veterinary medicines. AMA's members rely on this regulatory scheme to provide predictable, timely and science-based product assessments. These risks, outlined in the Government-commissioned *Cost Benefit and Risk Analysis of the Potential Relocation of the APVMA,* are occurring now.

Given the impact on APVMA performance, the Government Policy Order appears inconsistent with the general governance duties outlined in section 15 of the PGPA Act.

Australian agriculture industries and pet owners receive significant benefit from timely access to high quality and reliable veterinary medicines. The APVMA, through its assessment process, facilitates this access. While AMA recognises the efforts that have been made to date to help ensure that the risks associated with the relocation are minimised, it remains concerning that key risks – especially those relating to staff retention and recruitment – are now occurring.

AMA looks forward to working with all stakeholders to maintain APVMA's assessment capability.