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21 February 2020

Mr Keith Lockyer
Corporate Services
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

By email only: APVMAConsultation@apvma.gov.au

Dear Mr Lockyer

Re: Submission on APVMA Stakeholder Engagement Framework

On behalf of Animal Medicines Australia, I write to provide Animal Medicines Australia's submission to the APVMA Stakeholder Engagement Framework. AMA thanks the APVMA for the opportunity to provide feedback and looks forward to participation in APVMA forums and other consultative processes.

I note that the Industry Consultative Forum particularly will provide a formal mechanism for high level engagement between APVMA senior management and industry stakeholders. This forum has the potential to improve APVMA outcomes, address areas of inefficiency and identify problems and solutions to challenges within the veterinary product regulation process.

I note the Industry Consultative Forum provides a biannual opportunity for engagement with industry bodies, I stress the need for consultation and engagement with key stakeholders should not be limited to this forum. This engagement should be facilitated through open and accessible lines of communication, particularly with registrants who are generally the most affected by the operations of the APVMA.

Yours sincerely

Signed
Ben Stapley
Executive Director

SUBMISSION

APVMA Stakeholder Engagement Framework

February 2020

Animal Medicines Australia

Animal Medicines Australia

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.

Products from our member companies account for more than 90% of all animal health products sold in Australia.

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

In the companion animal sector, animal medicines facilitate healthier, longer and better quality partnerships between people and their pets.

Why it is important for the APVMA to conduct effective engagement and consultation with stakeholders?

As a regulator the APVMA provides certainty to the public regarding the efficacy, safety and quality of agricultural and veterinary chemicals registered in Australia. Similarly, AMA and its members are committed to ensuring that all animal health products meet the community's expectations of safety, efficacy and quality.

Effective, meaningful and systematic consultation processes create benefits for all stakeholders. These include:

- Minimising the impact of regulatory changes,
- Ensuring that proposals fully take account of views of, and impact on, key stakeholder groups, and
- Generating superior regulatory outcomes.

The Australian Government guidelines for Best Practice Consultation emphasizes that consultation should be used to improve decisions and will ensure an opportunity for stakeholders to contribute to policy development[1] in a positive way. In the case of the APVMA, effective consultation is essential to improving the regulatory environment for both the end users of registered products and for the registrants.

Why it is important for the APVMA to consult with AMA?

As the peak industry body for the animal health industry, AMA regularly engages with the APVMA, the Department of Agriculture and other stakeholders to promote the effective, independent and risk-based scientific regulation of veterinary medicines in a manner that supports innovation and investment in animal health.

AMA encourages the APVMA to employ consultation practices that are fully compliant with the Commonwealth Guidelines to Best Practice Consultation[2].

[1] The Australian Government Guide to Regulation, 2014 Canberra

[2] Guidance Note - Office of Best Practice Regulation, Department of the Prime Minister and Cabinet, 2016.

The APVMA Stakeholder Engagement Framework

Genuine, timely and properly targeted consultation will improve regulatory outcomes:

- **Genuine engagement with stakeholders** will include listening to, discussing with and taking feedback from both industry stakeholders and registrants of veterinary medicines. This will enable the APVMA to improve regulatory delivery and feedback systems.
- **Providing timely opportunities for engagement** will allow industry representative bodies to receive and collate feedback from members and provide a considered view for their sector.
- **Identifying the affected parties** and conducting targeted consultation will ensure the APVMA is engaging with relevant organisations and reduce consultation for consultation sake.
- By following best practice guidelines, the APVMA's consultation with other regulatory bodies should ensure that **duplication of regulation is minimised**.

Industry Consultative Forum

AMA supports the establishment of an Industry Consultative Forum.

AMA strongly supports regulatory processes which are developed in consultation with the groups most affected, and as such it is essential for APVMA to formally consult with the animal health industry.

By representing the interests of the animal health industry collectively, AMA as a body provides the APVMA with a considered view of challenges and opportunities for improvement in the regulatory environment.

AMA notes that previous APVMA industry consultative forums (such as the Industry Liaison Committee (ILC) and the Industry Technical Committee (ITC)) provided useful, formal and regular opportunities to discuss operational and technical matters between the regulator and interested stakeholders. While the APVMA has continued to consult in an ad-hoc manner since the abolition of the ILC, Animal Medicines Australia considers that it is now timely to re-establish more regular and routine consultation mechanisms.

Industry and Community Consultative Forum

The COAG principles for effective regulation[3] identify the need for genuine and timely consultation with affected businesses, community organisations and individuals. This principle is supported by AMA.

AMA would welcome further discussion with the APVMA regarding proposed funding arrangements for this activity. Noting the public good nature of the activity, this should not be subsidised by industry fees.

AMA encourages the APVMA to consider effective digital engagement mechanisms which are readily available options for engaging broader community groups. These options may potentially lower costs for the agency and facilitate engagement with identified stakeholders[4].

[3] The Australian Government Guide to Regulation, 2014 Canberra

[4] Guidance Note - Office of Best Practice Regulation, Department of the Prime Minister and Cabinet, 2016.

In Summary:

AMA supports timely, genuine and comprehensive consultation with industry in line with Australian Government Best Practice Consultation guidelines.

The Industry Consultative Forum is likely to provide a formal mechanism to directly discuss high level industry issues with the leadership of the APVMA, improve outcomes and address areas of inefficiency at the regulator.

The Industry and Community Consultative Forum will provide a useful forum for the APVMA to engage with a broad range of stakeholders beyond industry. Due to its functions, composition and nature, alternative funding arrangements other than subsidies from APVMA levies and fees should be applied.

While APVMA welcomes re-establishment of these committees, consultation by APVMA with all stakeholders should not be limited to biannual meetings. Meaningful consultation should occur in a timely way to allow peak bodies to engage with the APVMA for improved regulatory outcomes.