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Department of Prime Minister and Cabinet
Canberra ACT 2600

Online submission only via https://deregulation.pmc.gov.au/priorities/regulator-best-practice-and-performance/draft-regulator-performance-guide-consultation/make-a-submission

Dear Sir/Madam,

Re: Submission to Regulatory Performance Guide consultation paper

Thank you for the opportunity to provide a submission to the Regulator Performance Guide Consultation Paper (the consultation paper). We welcome the opportunity to assist the government in supporting regulation that is effective, efficient and fit for purpose, and consistent with government principles of best practice regulation.

Animal Medicines Australia (AMA) is the peak industry association representing Australia's animal health sector. Our members are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $28 billion dollar livestock industry and the $13 billion pet industry. AMA members represent more than 90% of registered veterinary medicine sales in Australia.

Our primary industry regulator is the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA is an almost entirely cost-recovered agency, funded by application and registration fees and levies from the regulated community. The APVMA has only recently emerged from a prolonged period of disruption and poor performance associated with its relocation to Armidale. Since then, however, the APVMA has employed well, attracting well qualified and technically proficient staff. AMA has observed a significant improvement in corporate culture and performance, with on-time application completion rates rising steadily from around 70% in 2017, to 99% in the last reported quarter (Oct-Dec 2020).

AMA sees the proposed Regulator Performance Guide as a valuable aid in protecting these gains and supporting further improvements in regulator efficiency and effectiveness.

We look forward to continuing engagement on this important topic. If we can provide additional information at this time, please do not hesitate to contact me.

Yours Sincerely,

(unsigned for electronic submission)

Dr Charmian Bennett
Director, Science and Policy

SUBMISSION TO THE

Draft Regulator Performance Guide

21 May 2021

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.

The regulation of veterinary medicine products in Australia must be efficient and effective so that Australian farmers and pet owners have timely access to the critically important animal health products that AMA's member companies provide.

AMA's member companies have a strong interest in ensuring that the regulator is able to deliver timely, predictable and efficient veterinary medicines approvals. An efficient and effective regulator is critical for the business and strategic planning of member companies and ensures that Australian animals have access to the world's leading veterinary medicine products. Australia is a small market (est. 2.2% of global sales) with significant regulatory costs and requirements. In some cases, these regulatory burdens are disproportionate to the risks that the products pose, potentially denying important benefits for animal health and welfare.

Post-market monitoring activities in Australia are further complicated by the responsibility of individual state and territory governments for control of use, and the overlap of compliance and enforcement activities between APVMA and the individual states and territories, leading to varying degrees of enforcement in different jurisdictions. This has resulted in notable inconsistencies and unpredictability in post-market compliance of veterinary medicines.

Principles of Best Practice Regulation

The discipline and rigor provided by the Australian Government's regulatory impact analysis framework encourages regulation that is appropriate, justified, properly targeted and proportionate.[1] AMA supports the Principles for Australian Government Policy Makers in this framework that apply wherever there is an expectation of compliance by the regulated community. Similarly, AMA supports The Council of Australian Governments (COAG) Principles of Best Practice Regulation.[2]

AMA agrees with the Australian Government's position highlighted in the consultation paper, that regulation is defined as "*any rule endorsed by government where there is an expectation of compliance*" and "*Rules can take many forms, not all of them the 'black-letter' kind*."

The Government's commitment to a stewardship approach to ongoing regulatory reform that ensures fit-for-purpose and rigorous regulation while reducing the regulatory burden is supported by AMA and our members. Similarly, AMA commends the Government for the recognition that regulation is not a one-size-fits-all activity and that, due to varying regulatory functions, resourcing and capabilities, individual regulators should draw on the proposed principles to develop tailored performance monitoring and reporting processes, in consultation with the regulated community. Ensuring that these processes are appropriate for the specific regulator role, remit and legislative environment and reflect outcomes-focussed performance measures will provide the animal medicine sector with

[1] Australian Government Guide to Regulatory Impact Analysis (2nd ed.)
[2] Best Practice Regulation: A guide for Ministerial Councils and National Standard Setting Bodies | Department of the Prime Minister and Cabinet (pmc.gov.au)

confidence that the APVMA's performance reporting mechanisms are fit for purpose and provide meaningful insight into its operations.

AMA supports the recommendation that regulators refer to the Department of Finance's *Resource Management Guide 131* for guidance regarding the development of performance measures and requirements for performance measures.[3] This Guide promotes the development of performance measures that consider the high level, strategic objectives or purposes that the regulator seeks to achieve and recommends that they:

- Relate directly to the regulator's purposes or key activities;
- Use reliable and verifiable sources of information and methodologies;
- Provide an unbiased basis for the measurement and assessment of performance;
- Comprise a both qualitative and quantitative performance measures, where appropriate;
- Measure outputs, efficiency and effectiveness, where appropriate; and
- Provide a basis for assessment of performance over time.

AMA agrees with the Government's view that regulators should aim to improve their performance, capability and culture while remaining flexible and responsive to changing circumstances. For example, the APVMA has had to modify and adapt its work strategies to enable business continuity from a remote location, alongside large staff turnover and loss of corporate knowledge, followed by significant operational disruptions to the regulator and its regulated community resulting from a global pandemic. AMA notes that these recent experiences of the APVMA have clearly demonstrated the importance of regulator flexibility and capacity to respond to change.

Industry has been particularly impressed by the willingness of the APVMA to consult with industry to develop mutually acceptable solutions to address disruptions arising from the pandemic. For example, COVID-related travel restrictions significantly disrupted manufacturing audit schedules, requiring a collaborative approach by APVMA with industry to maintain assurance of product quality standards under alternative audit arrangements, thereby ensuring the availability of critical animal health products during the pandemic.

It is important to acknowledge that some regulators, like APVMA, rely on highly specialised scientific and support staff and are especially vulnerable to significant change. This was clearly evident during the APVMA relocation and the pandemic. Further support for training and flexible working arrangements for regulatory staff would assist regulators in meeting the challenges associated with challenging and changing circumstances.

Principle 1: Continuous improvement and building trust – regulators adopt a whole-of-system perspective, continuously improving their performance, capability and culture, to build trust and confidence in Australia's regulatory settings.

The essential and rigorous work done by the APVMA in making independent, scientifically valid and respected decisions, is the foundation for positive outcomes for animal health and welfare, the environment, human health, worker safety, agricultural productivity, public health and food safety.

[3] Resource Management Guide 131: Developing Good Performance Information

Importantly, the independence of the APVMA gives confidence to Australian consumers, governments and Australia's vital trading partners.

AMA supports the Government's expectation that all regulators commit to continuous improvement in their processes, governance and capabilities and that they consider and aim to improve the combined regulatory burden of governments on business and the community. Efficient practices need to become embedded in the policy, approach, and operational systems under which regulators exist to allow continuous improvements.

AMA has previously recommended that the government promote and facilitate the development of a best practice regulatory culture that embraces and facilitates innovation, evidence-based decision-making, timeliness and predictability, efficiency and effectiveness, transparency, visible governance and accountability. These elements are essential to support efficient and effective regulatory oversight alongside high quality advice, programs and services.

The proposals included in the consultation paper and highlighted in the Department of Finance's *Resource Management Guide 131*[4] align with these recommendations. The necessary regulatory policy information, structures, tools and key Government policy statements exist to facilitate a best practice regulatory culture. In particular, AMA notes the critical importance of the Principles for Australian Government Policy Makers set out in the Australian Government Guide to Regulatory Impact Analysis (2nd ed.):[5]

Principles for Australian Government Policy Makers

- *Policy makers should clearly demonstrate a public policy problem necessitating Australian Government intervention and should examine a range of genuine and viable options, including non-regulatory options, to address the problem.*
- *Regulation should not be the default option: the policy option offering the greatest net benefit — regulatory or non-regulatory — should always be the recommended option.*
- *Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.*
- *Policy makers should consult in a genuine and timely way with affected businesses, community organisations and individuals, as well as other policy makers to avoid creating cumulative or overlapping regulatory burdens.*
- *The information upon which policy makers base their decisions must be published at the earliest opportunity.*
- *All regulation should be periodically reviewed to test its continuing relevance.*

These Principles provide a framework for evaluating the merits of legislative or regulatory proposals and ensure that regulatory responses are appropriate, properly targeted, effective and proportionate.

AMA supports the Government's recommendation that regulators build and maintain collaborative relationships with other entities within the regulatory system to identify and avoid regulatory duplication and overlap. Various entities involved in the regulation of agricultural chemicals and veterinary medicines have tended to undertake regulatory and operational reform processes independently of each other, with little or no consideration of the collective administrative burden

[4] Resource Management Guide 131: Developing Good Performance Information
[5] Australian Government Guide to Regulatory Impact Analysis (2nd ed.)

placed on their stakeholders to genuinely participate in the associated consultative and reporting activities.

Whilst the APVMA is central to the regulation of agvet chemicals in Australia, the regulatory management of veterinary medicines is part of a broader regulatory landscape for "chemicals" management, including:

- Dangerous Goods Transport (air, land, sea)
- Dangerous Goods Storage
- Chemicals of security concern
- Diversion to illicit drugs
- Retail storage
- Chemical Scheduling
- Biosecurity
- National Pollutant Inventory
- Contaminated land management
- GHS labelling and Safety Data Sheets
- Environmental impacts
- Work Health & Safety
- Australian Packaging Covenant
- Trade Measurement
- Waste management
- Trade waste
- International treaties and conventions

For the most part, other regulation is complementary or additive rather than duplicative. For example, Dangerous Goods Storage has requirements for site manifests and site plans at eligible locations. Chemicals of security concern processes are in place to minimise the risk of commonly available chemicals being used for terrorist purposes; similarly for chemical diversion to illicit drugs.

An ongoing issue where there is duplication, and thus, confusion, for veterinary medicines users, is due to the inappropriate addition of hazard information from the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) on risk-based product labels. Hazard information is not appropriate for defined use products, where the label directions for specific use patterns incorporate measures to mitigate the risks posed by a hazard. Overlaying the APVMA expert risk assessment with GHS hazard elements does not improve user safety and contributes to label clutter on already crowded labels.

Principle 2: Risk-based and data driven – regulators maintain essential safeguards, using data and digital technology to manage risks proportionately to minimise regulatory burden and to support those they regulate to comply and grow.

Australia's independent regulator for veterinary medicines, the Australian Pesticides and Veterinary Medicines Authority (APVMA), is globally recognised as being a scientifically competent and respected, risk-based regulator of agricultural chemicals and veterinary medicines. This includes pre-market approvals and on-going post-registration activities, including Good Manufacturing Practice (GMP), adverse experience reporting and pharmacovigilance.

The APVMA is a statutory authority of the Australian government specifically established in 1993 to centralise the registration of all agricultural and veterinary chemicals for the Australian marketplace. Prior to this, each State and Territory government had its own system of registration. Australia is a small market (est. 2.2% of global sales) with significant regulatory costs. A centralised, harmonised system is essential to support investment and innovation in animal health here.

The APVMA may *inform* policy but its core function is to *operationalise* and *implement* policy. The authority's principal responsibilities are described in the *Agricultural and Veterinary Chemicals*

(Administration) Act 1992 and the *Agricultural and Veterinary Chemicals Code Act 1994*. As the operational arm of policy, the APVMA needs to be able to evolve to deal effectively and efficiently with new science, technologies, methods, approaches and best practices. This requires an adept policy capability at the Department level.

The efficiency of the regulatory framework for agricultural chemicals and veterinary medicines has been scrutinised extensively in recent years and is currently subject to an independent review commissioned in 2019 by the then Minister for Agriculture, the Honourable Bridget McKenzie. As highlighted in the consultation paper and earlier in this submission, regulatory systems need to be able to progressively and continuously respond to changing circumstances and technological advances – not wait for a major review event.

AMA supports the Productivity Commission principle of 'minimum effective regulation' to ensure that regulatory actions are properly targeted, proportionate and implementable. Regulation should not be unnecessarily restrictive and the focus should be on the minimum level of regulation needed to meet regulatory requirements. Critical elements such as food safety, animal welfare, environmental protection and export market access require a comparatively high level of regulation as the minimum standard required to maintain trust and confidence in the system.

The consultation paper notes that "best practice regulators take a risk-based approach to operational policy development, administration and enforcement activities, informed by data, evidence and intelligence." AMA considers that the APVMA is generally proficient at developing risk-based and data-driven operational processes to implement government policy decisions. Further, APVMA has demonstrated a willingness to engage with industry to support the development and improvement of operational processes that are appropriate, achieveable and effective for the regulated community as well as the regulator.

Principle 3: Collaboration and engagement – regulators are transparent and responsive, implementing regulations in a modern and collaborative way.

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.

AMA supports timely, genuine and comprehensive consultation with industry that is fully compliant with the principles of best practice consultation developed by the Australian Government Office of Best Practice Regulation and outlined in the *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies* [6] and the *Australian Government Guide to Regulatory Impact Analysis*[7]. Key messages in these documents include:

- Consultation should not appear to be an afterthought. Consultation should be a natural extension of existing, well established lines of communication with stakeholders, and not sought out only when consultation is needed.

[6] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies (2021)
[7] Australian Government Guide to Regulatory Impact Analysis (2nd ed.)

- Consultation should capture the diversity of stakeholders affected by the proposal, including state, territory and local governments and government agencies. Other regulators with similar policy responsibilities and/or overlapping regulatory functions should always be consulted.
- Communication channels should be relevant and accessible to all stakeholders.
- Agencies should minimise the burden of consultation on stakeholders.
- The objectives of the consultation and its content should be clearly explained, including how and when the final decision will be made.
- Consultation processes should be consistent, flexible and demonstrate experience and professionalism.
- Consultation processes should be evaluated and reviewed to ensure ongoing relevance and effectiveness.
- Consultation should not be rushed. Stakeholders must be given sufficient time to gain a proper understanding of the issue/s and its implications so they can provide a considered and meaningful response.
- Consultation should be used to improve decisions, not as a substitute for making decisions.

These principles identify the need for genuine, meaningful and timely consultation with stakeholders to improve policy decisions, minimise the impact of regulatory changes and generate superior regulatory outcomes.

AMA regularly engages with the APVMA, the Department of Agriculture, Water and the Environment 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 notes that the APVMA, in particular, has demonstrated marked improvement in stakeholder consultation in recent years, resulting in efficiency benefits for the regulator and improvements to the regulatory environment for both registrants and users of veterinary medicines.

AMA supports the proposed principle regarding collaboration and engagement and the Government's position that best practice regulators are transparent and responsive, and implement regulations in a modern and collaborative way.

Performance reporting under the PGPA Act

The APVMA operates under an Intergovernmental Agreement[8] between the Commonwealth and the States. Under that agreement, the APVMA is responsible for regulating the supply of safe and effective agricultural chemicals and veterinary medicines in Australia, up until the point of sale.

The APVMA annual report includes an annual performance statement of the APVMA, as required under paragraph 39(1)(a) of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).[9]

AMA supports the proposal to remove existing duplication of responsibilities associated with performance reporting. Removing the requirement for regulators to produce a standalone performance report under the 2014 Regulator Performance Framework, instead requiring them to

[8] Intergovernmental Agreement (IGA) to COAG - Department of Agriculture

[9] Australian Pesticides and Veterinary Medicines Authority Annual Report 2019-20 (apvma.gov.au)

incorporate performance reporting into their existing reporting processes, will simplify reporting processes and improve clarity for stakeholders and the community. The proposed transitional year will assist regulators in adjusting to this new requirement and minimise any disruption experienced.

AMA supports the proposal to review the Regulator Performance Guide two years after its commencement and every five years following the initial review. Such a review program will ensure that the Guide remains fit for purpose and keeps pace with the rapidly changing environment in which AMA's members operate.

Summary

Animal Medicines Australia (AMA) supports the development of a Regulator Performance Guide to update the 2014 Regulator Performance Framework. AMA supports regulatory reforms to provide appropriate, proportionate, fit-for-purpose regulation that provides confidence for consumers, whilst reducing the regulatory burden on those who are regulated. The principles proposed in this draft Guide will support regulators to work in consultation with the regulated community to develop tailored, outcomes-focussed performance monitoring and reporting processes that are appropriate for its specific role, remit and legislative environment.