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

13 December 2019

APVMA GMP Review Team
Manufacturing Quality and Licensing
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Kingston ACT 2604

by email: mls@apvma.gov.au

Dear Review Team

Review of the management of the APVMA GMP Code

As a key stakeholder, Animal Medicines Australia (AMA) is pleased to have the opportunity to provide information to this review.

AMA is the peak industry body representing the leaders of the animal medicines industry in Australia. Its member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products to protect and treat animals with illnesses, diseases and injuries and promote animal welfare across the companion animal, livestock and equine sectors.

AMA members' products support up to 15% of livestock production output across major industries, contributing an additional $2.7 billion in added value and 9,900 FTE jobs.[1] Further, animal health products protect and promote the health of Australia's 28.5 million pets, resulting in longer, more beneficial and responsible relationships between pet owners and their animals.[2]

AMA works closely with its members, a variety of organisations, and governments to promote an evidence-based approach to public policy. Additionally, AMA advocates for the responsible and judicious use of all veterinary medicines to improve and protect animal health and welfare.

In the attached submission AMA focuses on enhancing some of the structural and administrative elements that set the APVMA and industry in a better position to address important governance, procedural, efficiency and effectiveness areas.

AMA will be pleased to further discuss any aspects.

Yours Sincerely

Unsigned for electronic lodgement

Ben Stapley
Executive Director

[1] Acil Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries 2015-16, June 2018
[2] Animal Medicines Australia (2019), Pets in Australia: A national survey of pets and people, October 2019

Review of the management of the APVMA GMP Code

13 December 2019

Animal Medicines Australia

Contents

1. Introduction

AMA recognises the role of Good Manufacturing Practice (GMP) both in the Australian context and with regard to other international sources and markets.

> "GMP ensures veterinary chemical products are consistently manufactured to the appropriate quality standards for their intended use—and in accordance with their registration particulars and specifications. It encompasses both the manufacturing process and quality control activities and processes to ensure they comply with the GMP Code."

AMA is supportive of this current review and believes that there is good opportunity to refine and enhance the governance, operation and management of some of the framework elements that can lead to improved transparency and performance.

In terms of scope, AMA contends that there is need to focus on components of the scheme rather than to attempt to provide holistic analysis and assessment at this time – there needs to be a staged approach. The size of the current work elements are too large to provide a manageable response.

As a basis for progress, AMA sees that reforms to the MLS-ILC could assist in providing the foundation for an energised and disciplined approach to meeting both APVMA and Industries needs.

In part, this could be achieved by tasking the MLS-ILC with a forward-agenda and workplans with use of the APVMA website to improve transparency and informed contribution. This is discussed under Item 4 below.

AMA sees this reform as contingent to establishing a short, medium and long term platform and processes to improved management of the Manufacturer Licensing Scheme.

2. Best Practice Regulatory Approaches

Since the introduction of requirements for regulatory impact analysis and regulatory impact statements in the 1990s there has been continuing evolution of the understanding of the critical importance of these tools in regulatory development. The Australian Government's Deregulation Agenda[1] notes:

- Regulations include any laws or other government-endorsed 'rules' where there is an expectation of compliance**.**
- Every policy proposal designed to introduce or abolish regulation must be accompanied by a Regulation Impact Statement (RIS).

Position[2]**:** Animal Medicines Australia (AMA) supports The Council of Australian Governments (COAG) Principles of Best Practice Regulation; the Ten Principles for Australian Government Policy Makers; and the Development of a Best Practice Regulatory Culture.

These principles are critical to ensure that regulatory responses are properly targeted and proportionate. They are supported by AMA as an essential framework which can be used to assess the merits of any legislative or regulatory proposal.

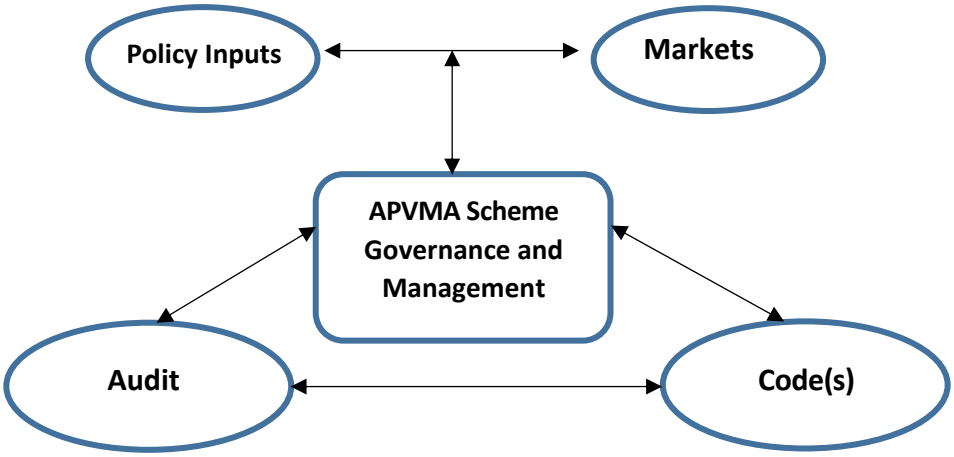
These principles provide a useful checklist in any regulatory development exercise.

[1] https://www.jobs.gov.au/deregulation-agenda
[2] https://animalmedicinesaustralia.org.au/wp-content/uploads/2019/10/02REGU1.pdf

3. *Simplified description of elements of the APVMA GMP Code*

To facilitate discussion Diagram 1 identifies a simplified depiction of the framework elements and some of the required characteristics and considerations.

Diagram 1: Simplified Diagram of some Elements of the APVMA Manufacturers Licensing Scheme



Considerations:

- Local, import, export
- Local auditors – numbers, experience, capabilities, continuity profile, coverage, availability with respect to industry needs
- TGA Auditors – availability, TGA-APVMA service-level-agreements?
- Consistency
- Issues resolution/advice/ consideration – e.g. time between inspections of O/S plants, updating APVMA country list to match MRA, UK MRA communication

Required Characteristics:

- Resourced
- Effective
- Responsive
- Actively managed
- Current, including MRAs
- Clear roles and responsibilities
- Collaborative
- Meaningful customer and Stakeholder engagement
- Metrics and success measures

Considerations:

- Market purpose
- Currency
- Revisions
  - updating
  - consultation
  - timelines
- Clear recognition of roles of the range of Codes i.e. local, import, export, regulatory, trade facilitation

4. *The role and composition of the Manufacturing Licensing Scheme Industry Liaison Committee (MLS-ILC)*

The MLS-ILC is described as:

> "The Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) is a forum for the APVMA to discuss with industry representatives and auditors strategic and operational issues relating to the Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice Scheme."[3]

[3] APVMA Annual Report 2018-19, p.40

The Terms of Reference[4] are to:

- obtain the views of industry members and auditors on issues of an operational, technical or strategic nature
- advance the development and review of operating procedures, manufacturing standards and guidelines relevant to the Australian Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice Scheme
- provide industry input into APVMA operational planning processes relating to manufacturing issues
- identify opportunities for regulatory reform within the existing framework
- consider the effect of proposed policy changes on APVMA operations, and implications for industry
- facilitate communication with industry and other stakeholders.

4.1 Need to review MLS-ILC description and Terms of Reference

Both the Committee description and the Terms of Reference could be updated to achieve specific time related outcomes through a defined forward agenda and workplans. Posting the forward agenda and workplans on the APVMA website would also assist to improve transparency and allow stakeholders to better plan contributions.

An active workplan for 2020-2021 might include:

- Complete a 5 year review of the APVMA GMP Code document and implement ….
- Review and recommend enhancements to the audit program
- Develop metrics for …..
- Contribute to the development of …..
- Provide technical advice on ……

In tasking the Committee in this way may prove to give a better return to both the APVMA and stakeholders. More focussed attention may lead to more concrete beneficial outcomes.

4.2 MLS-ILC Composition

AMA is supportive of suggestions to increase the membership to include a second representative from the industry association secretariats. AMA has had the opportunity of discussing this with its MLS-ILC representative. This would:

- provide an added skill set with a broad regulatory and policy contribution
- assist with active communication through industry communications and industry committees

4.3 MLS-ILC Meeting Frequency

The meeting frequency should be revisited as part of a review of the Committee description and Terms of Reference. There should be a commitment for at least one face-to-face meeting per year with additional meetings by Skype, teleconference or other means.

MLS-ILC Meeting dates should be established 12 months in advance to assist planning and to maximise participation by members.

[4] APVMA Annual Report 2018-19, p.40

5. *Audit management*

AMA understands that a Review of APVMA's GMP compliance program was undertaken in 2017. There appears to be some mention of this review on the APVMA website at https://apvma.gov.au/node/27786 but there is insufficient detail for stakeholders to be able to make an assessment of the findings.

In principle, there are a number of performance criteria that should be met in the audit process; including:

- Resourcing (numbers and coverage)
- Availability (temporal and geographical)
- Succession planning
- Consistency between auditors and between audit locations

A number of items are also identified under "Audit" in Diagram 1.

6. *The core elements of GMP, outlined in the GMP Code and Annexes*

AMA supports review of the GMP Code and Annexes as part of a considered approach by a reformed MSL-ILC.

7. *The scope of the GMP Code in the context of international schemes to support the export of products manufactured in Australia.*

From a regulatory principles perspective, there needs to be a distinction between:

- GMP to support the local market (local manufacture or import); and
- Requirements to support exports

The former being mandatory and the latter optional to meet trade requirements.

AMA supports review of international schemes as part of a considered approach by a reformed MSL-ILC.

8. *Clarification sought on EU Mutual Recognition Agreements (MRAs)*

For the core text, there are three key documents:

1) The original EU-AU MRA treaty that entered into force on 1 June 2001,
2) The amending treaty that entered into force on 1 January 2013, and
3) The EFTA MRA extending the treaties application to non-EU European countries (Norway, Lichtenstein, Iceland, Switzerland)

The new UK-AUS MRA (January 2019) simply references the circumstances existing under the EU-AU MRA with precisely the same scope and application. This means that conformity assessments, designating authorities and certificates under the European regime remain valid for the UK.

Territorial applicability: The language referred to in all these texts refers to the European Community. However, guidance issued by the EMA makes it clear that the territorial applicability is that it covers all European Union countries. See here for example. European Community appears synonymous with the EU. The status of Hungary itself is interesting. It entered into the Union in 2004, after the initial MRA, but before the 2013 Amendment. So, despite the fact that the Amendment treaty was negotiated by the EU

on behalf of all its member countries in 2012, the APVMA assumes that it is only applicable to those countries that were members in 1998/9. This doesn't seem a tenable position.

When a country joins the EU, it accedes to all legislation current in the EU. That would include legislation implementing the EC-Australia MRA. The MRA itself is with the EU – not with the collective member countries.

GMP Inspections: The MRA specifies that veterinary inspections will be conducted by the TGA on behalf of the APVMA against the Australian Code of GMP and the European guide for veterinary medicinal products. Should APVMA begin to carry out inspections itself, these will be routinely transmitted to the importing Party until there has been a satisfactory verification of the APVMA GMP inspection program.

This seems to imply that there may not need to be an amendment to the MRA only 'satisfactory verification of APVMA audits.

APVMA clarification would be welcomed.

9. Recommendations to ensure adequate consultation on any proposed changes to the GMP Code

AMA supports review as part of a considered approach by a reformed MSL-ILC.

AMA supports regulatory best practice approach it is essential that APVMA suggested changes be support with clear justifications for change.

10. The type and frequency of further support, if any, that should be provided to manufacturers or auditors to ensure compliance with the GMP Code.

AMA supports APVMA engagement with its regulated stakeholder and suggests 2 sessions per year in major centres.

Recommendations

AMA is pleased to make the following recommendations:

Recommendation 1: APVMA work with industry to reform the MLS-ILC that includes:

- Review of the Committee description (purpose) and Terms of Reference.
- Task the MLS-ILC to develop a forward agenda and annual workplan.
- Increase the membership to broaden the regulatory skill set.
- Develop a web-based resource for transparency and to facilitate an informed client base.
- Increase meeting frequency to at least 3 with one being face-to-face.

Recommendation 2: Adopt COAG best practice regulatory principles as working criteria in development and program review.

Recommendation 3: Develop and articulate required characteristics, metrics and success measures for the scheme.

Recommendation 4: In program development identify regulatory requirements and what may be trade facilitation. This is particularly important when considering the scope of the GMP Code in context of international schemes to support exports.

Recommendation 5: A reformed MLS-ILC consider a staged approach to review of the program elements; setting clear priorities.

An early priority might include audit management.

Recommendation 6: APVMA develop a series of regulated stakeholder sessions in major centres