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Australian Pesticides and
Veterinary Medicines Authority
GPO Box 3262
SYDNEY NSW 2001

Submitted by e-mail: CRIS2019@apvma.gov.au

Dear Sir/Madam

Australian Pesticides and Veterinary Medicines Authority (APVMA)
Draft Cost Recovery Implementation Statement (CRIS)

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

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. Our membership includes both multinational and Australian-owned companies dedicated to producing high-quality, safe and effective veterinary medicines.

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, other organisations, and governments to promote an evidence-based approach to public policy. We advocate for the responsible and judicious use of all veterinary medicines to improve and protect animal health and welfare.

[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.

The APVMA is a central pillar of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) that was established under Commonwealth, state and territory legislation. Under this arrangement, the APVMA has a clearly defined role as the regulator responsible for assessing and registering pesticides and veterinary medicines proposed for supply in Australia. In essence, the APVMA has responsibility and jurisdiction to the point of sale.

The NRS is currently under review following the 5 September 2019 announcement by Senator the Hon. Bridget McKenzie, Minister for Agriculture, who has appointed an independent panel of experts in regulation, agricultural production, veterinary medicines and human health to comprehensively review the regulatory framework for agvet chemicals.

Statements attributed to Minister McKenzie[3] include:

> "The review will examine the agvet chemical regulatory framework's aims, structure and operation, and make recommendations to ensure that it is contemporary, fit for purpose and reduces unnecessary red tape.
>
> In undertaking the review, the panel will:
>
> 1. assess the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme
> 2. consider what the goals of Australian agvet chemical regulation should be
> 3. consider the current and future requirements of Australia's regulatory framework for agvet chemicals
> 4. provide recommendations for reform of the regulatory framework to increase the value of Australian agriculture.
>
> The panel will have regard to regulatory roles and responsibilities at the national, state and territory level; interactions with other regulatory schemes and arrangements; any relevant domestic or international issues; any recent changes to the current framework, including reforms agreed by the Council of Australian Governments; and the government's agenda to reduce red tape wherever possible."

This is an important review and anticipated to provide an objective assessment of the NRS and appropriate recommendations for improvements. It also provides helpful context for the APVMA CRIS consideration.

AMA supports a robust, effective and efficient regulatory scheme for veterinary medicines regulation. Such a scheme is critical to ensuring attainment of the attributes the APVMA's describes of its role[4]:

> "We ensure Australians have access to safe and effective agricultural and veterinary (agvet) chemicals to control pests and diseases on animals and plants.
>
> We also monitor and enforce compliance with the Agvet Code and other legislation we administer.
>
> The APVMA keeps a Record and Register of approved agvet constituents, registered products and approved labels."

[3] https://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/independent-review-agvet-chemical-regulatory-framework

[4] https://apvma.gov.au/node/37

AMA supports the concept of the APVMA as a trusted and best-practice regulator of pesticides and veterinary medicines that has the respect and confidence of governments, the community, the rural sector, chemical users and the chemicals industry.

AMA recognises the need for the regulatory system to be properly resourced. Where appropriate, this includes recovery of the efficient costs of regulation from the regulated industry as determined by government policy.

Notwithstanding, AMA has specific concerns with both the process and substance of the APVMA draft CRIS. Issues identified for resolution include those detailed at *Attachment 1* to this letter.

AMA, representing industry regulated by the APVMA, asserts that holders should not be liable for costs over and above the efficient administration of the regulatory scheme.

APVMA's draft CRIS outlines that the agency's expected expenditure will, in the absence of changes to income and expenditure, result in a continued decline in the APVMA's cash reserves. APVMA has proposed three options (summarised at *Attachment 2* to this letter) to address the shortfall. Each option seeks to increase APVMA income through a combination of increases to annual product registration fees and application fees for assessments.

AMA's review of the draft implementation statement has highlighted multiple issues that should be addressed before implementing changes. These issues include the effectiveness of stakeholder engagement and the impact on industry.

Consultation and stakeholder engagement

AMA's consideration of the proposed increases in fees has been constrained by the consultation process used. While pricing changes have been discussed with industry, the Government's cost recovery policy is underpinned by three core principles that must be applied across all stages of the cost recovery process:

- Efficiency and effectiveness,
- Transparency and accountability,
- Stakeholder engagement.[5]

The stakeholder engagement process chosen by the APVMA has limited discussion of opportunities for cost savings through efficiencies, nor allowed proper scrutiny of the assumptions underpinning the cost model.

Based on the information available, it is not clear that any increase in fees and charges is justified. AMA proposes deferring the proposed implementation to facilitate greater stakeholder engagement at all stages of the cost recovery process and to allow objective consideration of APVMA's financial position both now and moving forward.

Impacts on Industry

All options proposed by the APVMA involve short lead times before changes to fees commence. This has negative consequences for business planning, product development and marketing plans that will need to be revised to accommodate increased product registration and application fees and charges.

[5] Australian Government Department of Finance, Australian Government Guidelines, Resource Management Guide No.304, p7.

Reviews and opportunities for increasing efficiency

Since 2013, there have been at least five separate reviews that have considered APVMA cost recovery arrangements. Each has made recommendations to improve the operational efficiency of the agency. Many recommendations, if implemented, would affect the cost base of the APVMA's operations. The impacts associated with proposed reforms should be taken into account when developing the cost model.

AMA's view is that any increase in should only occur after all requirements of the Australian Government Cost Recovery Guidelines have been met and increased operational efficiencies have been achieved. AMA looks forward to working with the APVMA towards resolution of these outstanding issues in a timely manner.

Next steps

AMA and its members recognise the challenges that the APVMA faces in reviewing its cost recovery structure. AMA members are committed to working with the APVMA to implement a cost recovery model that meets the needs of both the APVMA and AMA members. AMA encourages the APVMA to genuinely engage with industry to :

- re-evaluate the cost model and the assumptions that underpin it,
- actively identify opportunities to use modern technologies to reduce costs, and
- defer implementation of any changes to fee structure until the cost model can be revised.

AMA looks forward to working with the APVMA to resolve these outstanding matters as a matter of priority. Should you have any questions regarding the content of this letter, please contact me.

Yours Sincerely

Unsigned for electronic lodgement

Ben Stapley
Executive Director

Attachment 1: Identified issues for resolution

Identified issues

- The Cost Recovery Model used in the CRIS may not reflect the contemporary needs of the regulated industry and sustainability for the APVMA. The evaluation of the previous cost model conducted by the APVMA has not been shared with stakeholders. It may no longer be relevant to current circumstances.
- The short consultation period on the APVMA Cost Recovery Implementation Statement has not allowed consideration of key issues such as opportunities for cost savings through efficiencies rather than continual increases in revenues.
- The 2017 PWC Review[6] made twelve recommendations and observations regarding APVMA's cost recovery arrangements; including of the type:
  - "The current cost recovery model is complex, outdated and needs to be updated, the prices set are no longer consistent or reflective of the true costs of undertaking activities."
  - "The APVMA does not currently have a process in place to accurately forecast the workload of applications and the modular break up by activity it expects to undertake."
  - "The methodology applied was consistent with past activity-based costing reviews and provides a good basis for comparison. Generally though, it should not be relied upon as the basis for adjusting the prices of the modules or items, noting the findings raised through the report."

  The status of several observations and recommendations remains unclear.
- The draft CRIS does not provide sufficient information for stakeholders to comment on key components of the APVMA's costs, including Activity Based Costings, costs of maintaining a separate Canberra Office and its longevity and ongoing staffing levels.
- The proposed implementation of new fees arrangement by 1 March 2020 would create significant difficulties for registrants as increases have not been included in current budget cycles
- Since 2013, Government and industry have made significant investments to modernise the agency. This includes $11 million committed in the 2017 budget to digitise and modernise APVMA systems as part of its relocation. It is unclear what dividend from this investment has been included in the updated cost model.
- Efficiencies achieved in APVMA operations including automating business processes, decreasing the size of the corporate services team do not appear to be reflected in the APVMA's cost model. This may result in over-recovery of costs.

[6] Australian Pesticides and Veterinary Medicines Authority Review of Cost Recovery Arrangements. Final Report October 2017

Principles for cost recovery

The Australian Government Cost Recovery Guidelines (CRGs) set out the overarching framework under which government entities design, implement and review cost recovered activities on behalf of the Australian Government.

The principles[7] include:

- Efficiency and effectiveness
- Transparency and accountability
- Stakeholder engagement

The cost recovery requirements include:

- Government policy approval to cost recover
- Statutory authority to charge
- Alignment between expenses and revenue
- Documentation and reporting
- Portfolio charging review

The CRGs provides guidance on each stage of the cost recovery process:

- Stage 1: Policy approval to cost recover
- Stage 2: Cost recovery model and CRIS
- Stage 3: Implementation
- Stage 4: Portfolio charging review

AMA contends that there is significant activity required at Stage 2 before progressing to Stage 3. However, the CRIS makes that leap without the necessary underpinning.

Cost model revisions foreshadowed but not delivered

The 2017-2018 APVMA Corporate Plan identifies:

- "As the agency prepares to relocate to Armidale in 2019, changes to the business model must be appropriately costed. In the forward horizon, the agency will engage industry in a review of its cost recovery arrangements with the release a cost recovery impact statement for consultation to ensure a sustainable funding model for APVMA's regulatory operations." *(underlining added)*

The 2018-2019 APVMA Corporate Plan identifies:

- "Once we have established our operations in Armidale, a formal cost recovery impact statement will be prepared. We will engage industry in consultation on the review of our cost recovery framework so that we can ensure a sustainable funding model for our future regulatory operations."
- "Responsible financial management of APVMA operations, including maintenance of positive equity balance until the implementation of a renewed cost recovery fee structure can assist to return reserves to $7.0 million for future operation." *(underlining added)*
- "A 2017 report on APVMA funding and cost recovery identified an imbalance between current revenue and expenses (PricewaterhouseCoopers, 2017). Preparatory work to determine our cost base will enable a dialogue with industry on an appropriate funding model that reflects the changes in business process and the resources required to deliver modern regulatory services." *(underlining added)*

In the 2019-2020 Corporate Plan the language changed to:

- implement outcomes from the Cost Recovery Implementation Statement (CRIS)

[7] Australian Government Cost Recovery Guidelines, Department of Finance, Resource Management Guide No. 304 July 2014

Whilst the CRIS states "Standard Activity Based Costing (ABC) methodology was used to allocate expenses to activities and activity costs to outputs (services) using volume-based cost drivers" the ABC has not been made available for consultation with stakeholders.

Reviews of APVMA cost recovery

A range of reviews of the APVMA, including those below, have been undertaken. There is important need to take a consolidated approach to ensuring take-up of relevant recommendations.

- Department of Agriculture, First Principles Review of Cost Recovery at the Australian Pesticides & Veterinary Medicines Authority. Consultation Paper, November 2013 (Protiviti Report)
- Australian Pesticides and Veterinary Medicines Authority Review of Cost Recovery Arrangements. Final Report October 2017 (PWC)
- Independent Review of Assessment Performance REPORT AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY FINAL 22 DECEMBER 2017 (Reason Report)
- Australian National Audit Office (ANAO) Performance Audit 2016-17
- ANAO Report No.56 2016–17 Pesticide and Veterinary Medicine Regulatory Reform

Cost model uncertainties and clarifications

It remains unclear how APVMA business model might adapt to rapidly changing circumstances, such as technical innovations or demand for regulatory services.

It is unclear how some relocation costs have been treated in the cost model, including costs associated with retaining a satellite Canberra office and digital transformation supplier costs.

Discrepancies between draft cost model and draft implementation statement suggest stated efficiencies not included, creating a risk of over-recovery of costs[8].

Unclear how the impact of higher than usual employee costs associated with relocation have been excluded from analysis of cost base.

Consultation

AMA is committed to working with the APVMA to achieve a positive and sustainable cost recovery model for the APVMA.

[8] Draft APVMA CRIS cost model suggests Corporate Services at 37FTE, and CRIS suggests 25FTE. APVMA on-costs at 25%.

Attachment 2: APVMA Cost Recovery Options

Extract from APVMA Draft Cost Recovery Implementation Statement (CRIS)

Option 1

This option relies on all current regulatory service charges being maintained without amendment and includes the full impact of a price increase for the annual registration fee to $550 in FY2019–20. This fee will increase to $770 in FY2020–21 and to $875 in FY2021–22.

Option 2

This option includes nil impact of any calculated price decreases to Modules and Items but capping all calculated price increases for Modular applications at 50 per cent (vis a vis current prices). All other regulatory service prices will be maintained at current levels. The price for the annual registration fee will rise to $550 in FY2019–20, $710 in FY2020–21 and to $815 in FY2021–22. While the impact of the application fee increases will only be partial in 2019–20, the impact of the registration fee increase will be in full.

Option 3

This option is based on achieving close to parity in increased revenue from annual product registration fee and product application fee sources each year. In order to achieve this, registration fees will increase as follows:

- 2019–20: $550
- 2020–21: $600
- 2021–22: $650.

Application fee increases are currently capped at 72.5 per cent but will need to increase annually. Current expectations are that Item and Module fees will need to be adjusted annually, with price increases capped, to generate revenue from application fees close to equal the revenue expected from annual registration fees. Note that there will be nil impact of any calculated price decreases to Modules and Items, same as for Option 2.