Animal Medicines Australia

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Ms Annie Ryan
Chief Financial Officer
Australian Pesticides and Veterinary Medicines Authority
Canberra ACT 2601

Submission by email to CostRecovery@apvma.gov.au

4 September 2026

Dear Ms Ryan,

Cost Recovery Implementation Statement (CRIS) 2027-28.

Thank you for the opportunity to present our perspectives on the APVMA's proposed Cost Recovery Implementation Statement for 2027-28.

Animal Medicines Australia offers in-principle support for the proposed shift to full fee upfront cost recovery. However we note a number of concerns with the funding model used to develop the CRIS and consider that the CRIS may deliver negative unintended consequences that will limit the introduction and supply of innovative and new veterinary medicines to the Australian market. We have made a number of recommendations in our submission to mitigate these risks and support our industry to adjust to the new funding arrangement.

I would be pleased to discuss any of the points raised in our submission with you at any time.

Please do not hesitate to contact me if further information or clarification is required.

Yours sincerely,

Ben Stapley
Chief Executive Officer

SUBMISSION ON THE COST RECOVERY IMPLEMENTATION STATEMENT (CRIS): Australian Pesticides and Veterinary Medicines Authority

4 September 2026

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Animal Medicines Australia

Animal Medicines Australia (AMA) is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. Our members include local companies and divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $40.5 billion livestock industry and 31.6 million pets. Our members represent approximately 80% of registered veterinary medicine sales in Australia.

1. Executive Summary and Recommendations

Animal Medicines Australia (AMA) welcomes the opportunity to present our perspectives on the APVMA's proposed changes to its cost recovery framework. AMA seeks a framework that:

(i) Is consistent with established Government principles for cost recovery activities and the Government's charging framework,
(ii) Supports an innovative, profitable and productive animal health sector,
(iii) Supports access to new and innovative animal health products while minimising risks to users, consumers, animals and the environment, and
(iv) Supports the efficient administration of the Agvet Code.

In principle, AMA supports cost recovery of the efficient costs of administering the Agvet Code and the move away from a cost recovery framework that imposes unavoidable and undesirable cross-subsidies.

AMA supports the recovery of the efficient regulatory costs of the APVMA, but considers that the CRIS modelling is based on inefficient regulation in multiple areas. This is inconsistent with the Government's Cost Recovery Policy (CRP) and will result in the over-recovery of costs.

In accordance with the Government's cost recovery principles and policy, the proportion of costs resulting from inefficiency should not be subject to cost recovery from industry. The CRP also notes that efficiencies should be realized *before* seeking higher fees from the regulated industry. AMA supports only those costs necessarily incurred from the efficient operation of the APVMA. AMA encourages the APVMA to review the CRIS and exclude costs that stem from inefficient APVMA practices and processes.

AMA is concerned that the proposed implementation of the new cost recovery framework will result in undesirable and detrimental impacts on product availability, innovation and regulator performance. These include:

1. Sudden, significant increases in application fees that will drive large numbers of poor quality and under-prepared applications to be submitted just prior to 1 July 2027,
2. Disincentivising products with small projected sales to address local treatment needs, leading to gaps in available tools for veterinarians and negative animal health outcomes, and
3. Deferring the introduction of innovative new technologies as companies bypass Australia and prioritise registration in competitor markets with more beneficial and cost-effective regulatory arrangements.

AMA urges the Government and the APVMA to amend the planned implementation of the new CRIS and consider measures to minimise the negative, unintended impacts of sudden and significant changes to application fees.

This submission makes seven recommendations and two critical policy responses that are now essential to support an innovative animal health sector while ensuring appropriate funding for an independent, rigorous and efficient veterinary medicines regulator.

1.1 Recommendations

While AMA supports the policy change to cost recovery in principle, AMA urges the APVMA to adopt implementation measures that minimize the negative consequences of sudden, significant increases in fees to ensure continued access to innovative veterinary medicines that support animal health and welfare, biosecurity, farm productivity, food safety and market access.

Recommendation 1

APVMA should reduce all proposed increased fees and levies to recognize inefficiencies in current APVMA operations.

While AMA recognizes that the change in cost recovery policy necessitates increased fees, APVMA's proposed fees and levies for regulatory functions incorporate significant inefficiencies. AMA observes that staff levels since 2020 have trended upward, whilst timeframe performance has declined, despite no increase in work in progress. The observed decline in productivity indicates systemic inefficiencies that should not be subject to cost recovery. AMA requests that APVMA critically evaluates the data obtained from its Performance Enhancement Initiative project to streamline assessment processes to the minimum necessary steps to satisfy legislative criteria, and revise all application fees to reflect current operational inefficiencies.

Recommendation 2

APVMA should phase-in implementation of higher application fees over three years.

A gradual transition to higher application fees will:

- Facilitate business planning for higher fees,
- Ensure higher quality applications are submitted by minimizing cost incentives to submit applications immediately before application fee increases, and
- Minimise disruption to current product registration plans and innovation agendas.

Recommendation 3

Product application fees should be payable in installments across timeframes.

For applications where the assessment timeframe is longer than three months, the APVMA should schedule payment of application fees across three time points:

a. 30% of the full application fee should be payable at the commencement of the assessment (*after* Preliminary Assessment has been completed),
b. 30% of the full application fee should be payable at the half-way point of the assessment timeframe, and
c. 40% of the full application fee should be payable on finalization of the application.

Increased assessment fees represent a significant capital investment for many companies, and full up-front payment of fees represents a pre-payment for regulatory tasks that may not be completed for months or years. This creates an additional opportunity cost for companies that increases the real cost to applicants. This can be minimized by spreading payment increments to approximate the distribution of work required by the APVMA across the timeframe of the application.

Recommendation 4

APVMA should confirm any changes to fees and levies payable by applicants and registrants at least 12 months from the proposed change taking effect.

Rapid changes to regulatory fees disrupt business planning and impose additional costs as product schedules and launch plans are disrupted. A minimum notice of 12 months in advance of changes will minimize these impacts.

Recommendation 5

APVMA must reduce the levy rate for all veterinary medicine sales to 0.15%.

Higher levy rates for products with low sales volumes is inconsistent with a full up-front fee cost recovery model.

Recommendation 6

APVMA should create alternative registration pathways to reduce application fees for products with projected low annual sales.

AMA encourages APVMA to adopt partial fee waivers to support registration of niche products (with predicted annual sales of less than $1m annually). Approximately 80% of registered animal health products turn over less than $1m annually, and full up-front fees create a high risk that many of these products would not have been commercially viable for registration under a full fee model. Lack of product diversity and availability will have significant animal health, biosecurity, productivity, welfare and food safety implications.

Recommendation 7

APVMA should review assessment timeframes for all technical application types to ensure that the regulated timeframes reflect the amount of assessment work required by the APVMA.

Reductions in assessment timeframes, when delivered predictably by the APVMA, can offset some of the increased application fee by enabling a faster pathway to registration and subsequent sales. All assessment timeframes should be based on the minimum time needed for efficient assessment of the legislative criteria (not how long that process currently takes).

1.2 Critical Policy Responses to Support Innovation

The transition to a full up-front cost recovery framework highlights that changes to the veterinary medicine policy framework are now essential and time critical to avoid major negative consequences from changes to the APVMA fee and levy structure. These changes are essential to both:

- Maintain an incentive for multinational companies to bring their latest innovations to the Australian animal health market, and
- Support a diverse, productive and innovative local veterinary manufacturing industry providing essential animal health resilience and capability.

As a matter of priority, AMA urges the government to make two critical legislative and policy changes to support continued Australian innovation in animal health:

Critical Policy Response 1

The government must act on the need for improved data protection provisions for veterinary medicines. Current arrangements significantly lag key comparator markets in North America and Europe, hindering incentives for companies to introduce new technologies to a small market like Australia. AMA urges the government to increase legislative data protection periods for animal health products to 10 years, in line with overseas markets. This legislative amendment must be in place *before* increased cost recovery fees take effect.

Critical Policy Response 2

The government must direct the Agvet Chemicals Taskforce under AGSOC to review, as a matter of priority, arrangements for compounded medicines to ensure that veterinary compounding rules are not being inappropriately exploited to produce medicines that by-pass legitimate APVMA scrutiny. Increased APVMA fees will increase commercial incentives to exploit veterinary compounding loopholes.

1.3 AMA Position on Specific Elements of the CRIS

Upfront full-fee cost recovery

AMA's in-principle support of the policy change to upfront full fee recovery and associated reduction in sales levy is conditional on APVMA and Government implementing these changes in a manner that minimises the undesirable side-effects of a sudden and significant change to application fees. AMA notes several potential risks from a sudden change, including disincentivisation of innovative and niche products, whilst promoting the production and use of illegal and unregistered veterinary products.

AMA encourages APVMA and Government to ensure that inefficiencies in the regulation of the Agvet Code are not included in costs to be recovered from industry, in accordance with the Australian Government Cost Recovery Policy.

Reduced sales levy

AMA supports the reduction in sales levy. Sales levies represent an ongoing and unlimited tax on animal health product sales. However continuation of the tiered levy structure under a full fee recovery model is no longer justified and will disproportionately penalise small volume sales. The levy tiers should be removed and replaced with a single, equitable levy rate of 0.15% for all sales. This recognises that a tiered levy structure is no longer applicable in a full fee upfront cost recovery model.

Government appropriations

AMA welcomes greater government funding to support emergency use permits, and some other permit activities, in the new CRIS. Whilst industry accepts a cost recovery arrangement to register products and obtain market access in Australia, AMA considers that the costs of regulation should be

distributed across all those who benefit from that regulation, not just the registrants. AMA would welcome greater government funding to enable the provision of efficient regulatory services by APVMA (especially its ICT systems) and support functions that provide benefit to the broader Australian community (APVMA's monitoring, compliance and enforcement activities).

Separation of fees for agricultural chemicals and veterinary medicines

AMA supports the differentiation of fees for agricultural chemicals and veterinary medicines. Different fees should more accurately reflect the different amounts of work required to assess different product types and is consistent with the Government's Cost Recovery Policy that the registrant is charged only for the costs incurred in assessing their product. Different fees will also assist in addressing cross-subsidisation across other APVMA activities.

While supporting separation of fees between agricultural chemicals and veterinary medicines, AMA seeks to ensure that a consistent approach between the two is applied. AMA notes that work that should be similar or identical across agricultural and veterinary products (such as chemistry assessments) should incur similar costs. AMA is concerned that the different fees for chemistry assessments are not adequately explained within the CRIS and that this raises questions about the integrity of the underlying data used to inform the cost model.

Annual fee adjustments

An annual CRIS process is not supported by AMA. A CRIS process is complex and time-consuming, and the resource commitment required from the regulator, government and industry to undertake a full CRIS each year is not justifiable. Frequent CRIS also create greater uncertainty and unpredictability for companies. A CRIS process is more appropriately used at 3-5 year intervals in order to provide stability and certainty in funding arrangements to support innovation, research and development, registration pipelines and business planning over multiple years.

The proposed management of annual incremental fee changes via indexation, when justified, is supported in principle by AMA as it will assist APVMA to ensure fees remain aligned with the actual costs of providing that service. However indexation should be linked to agency productivity and efficiency. AMA notes that the modelling underpinning this CRIS is based on inefficient regulatory processes and therefore likely represents over-recovery of the efficient costs of regulation. Improved efficiencies should reduce the cost of providing that regulatory service, such that indexation may not always be needed to align fees with actual costs.

1.4 Key Concerns

Implementation on 1 July 2027

AMA has concerns with the proposed implementation of the new cost recovery arrangements on 1 July 2027, leading to unintended negative consequences. AMA strongly encourages APVMA to phase-in the new fees over a three-year period, stagger the payment of fees across the assessment timeframe, and ensure that any fee changes are confirmed a minimum of 12 months in advance of implementation.

Impacts on APVMA workload

AMA anticipates that there will be an increase in applications submitted immediately prior to 1 July 2027. This is likely to include applications that will be rushed to submission in order to secure lower fees before the fees increase. This will impose a significant workload on APVMA to process more applications than usual at the same time, and is likely to include poor quality applications that subsequently require additional work by APVMA to formally request missing information. AMA anticipates that this will place a significant burden on a regulator that is already struggling to meet its performance obligations.

Impact on local innovation

Innovation, research and development, and registration planning, are multi-year efforts. The new CRIS model risks the cancellation of current and future projects for new products and local innovations that are already underway. This risks Australia being demoted in international rankings and being overlooked for future investment and registration of new products.

Impact on niche products

AMA is concerned that the new CRIS model will support blockbuster products, generics and compounded products, at the expense of small to mid-range products that address important animal health needs in the Australian market. High upfront fees will act as a barrier to niche products with a limited market and the reduction in sales levy will offer minimal benefit to the registrant in return.

Lack of accountability measures

AMA notes the absence of mechanisms to incentivise regulator performance and deliver meaningful efficiencies. The CRP only requires APVMA to report on the performance of its cost recovery arrangements, not the efficiency of the work carried out under those arrangements. AMA seeks a stronger focus on regulatory performance and service standards, with greater accountability of the APVMA when its legislated timeframes are not met. Timeframe performance is critically important to registrants and even small delays by APVMA can lead to significant adverse commercial and animal welfare impacts.

2. Introduction

AMA recognises the APVMA as a trusted, independent and best-practice regulator of veterinary medicines, where decisions are based on scientific evidence and risk analysis, and whose decisions are respected by government, industry and the community. We support the need for APVMA to be appropriately and efficiently funded so that it can execute all of its regulatory and legislative obligations and responsibilities.

AMA notes that the Government has made a policy decision that requires the APVMA to recover the full costs of product assessment and registration for application fees. This is a significant change from previous arrangements, where application fees represented only 40% of the total assessment cost and the remaining 60% of the assessment cost was recovered over time from sales levies imposed on the product after registration.

This approach resulted in a series of undesirable cross subsidies where successful products with high sales would pay levies that exceeded the costs to the regulator of their assessment and registration. For products with very low or no sales, the costs of their registration would never be fully recovered.

Industry accepts the government policy for registrants to contribute to an efficient and effective regulatory system through a cost recovery system. However, the cost of animal health innovation continues to increase, creating challenging circumstances for companies to recoup high research and development costs, especially with short data protection periods and competition from compounded products. High registration fees and unique registration requirements for the small Australian market create further barriers that limit the availability of veterinary products.

The costs of registration and market entry are already high relative to market size, which has a disproportionate impact on innovation and can discourage the introduction of new veterinary products to Australia. Our industry supports a regulatory system that recognises and reflects the unique challenges posed by the Australian animal health operating environment and supports innovation in Australia's valuable agricultural and pet industries. AMA supports a cost recovery framework that is effective and equitable, and expects the regulator to be transparent about its charging framework and accountable for delivering its services efficiently. AMA's recommendations seek to ensure consistency with the Governments cost recovery policy, maintain incentives to innovate, protect the integrity of the veterinary medicines regulatory scheme and ensure continued access to critical tools required for veterinarians, pet owners and farmers.

AMA seeks to ensure that its contribution to regulatory functions supports rigorous, science-based assessments whilst maintaining incentives for industry to bring innovative and niche products and technologies to the Australian animal health market.

3. Efficient Cost Recovery

AMA supports an independent and efficient regulator that is appropriately resourced to deliver high quality, timely, rigorous and accurate assessments on time, where its decisions are based on scientific evidence and risk assessment. AMA notes and supports the critical importance of the independence of the regulator in making regulatory decisions.

AMA expects that implementation of this CRIS will adhere to government policy and guidelines for efficient and effective cost recovery.[1] To ensure consistency with the Government's Cost Recovery Policy (CRP), AMA seeks to ensure that:

- The regulatory system should be appropriately resourced to enable efficient recovery of the costs of regulation from the regulated community.
- Cost recovery charges should be closely linked to a *specified* activity.
- Registrants should not be liable for costs over and above the *efficient* administration of the regulatory scheme.

[1] Australian Government Cost Recovery Policy – Australian Government Cost Recovery Policy | Department of Finance

- The core principles of cost recovery policy should be (1) efficiency and effectiveness; (2) transparency and accountability, and (3) stakeholder engagement.
- Operational efficiencies directly affect the cost base of APVMA's operations and must be considered when developing the cost model.
- Any increases in fees and charges must be justified. Stakeholders should be able to scrutinise the assumptions underpinning the costing model, and be given appropriate and sufficient opportunities to do so.
- Increases in fees should only be considered *after* all requirements of the Australian Government Cost Recovery Guidelines have been met *and* increased operational efficiencies have been achieved.
- Changes should have appropriate lead-times before they commence.

The Ministerial Statement of Expectations[2] notes that the APVMA is expected to achieve its regulatory objectives efficiently and effectively, *minimising the cost recovery burden on industry*. This is explicitly echoed in the APVMA's Regulator Statement of Intent, confirming APVMA's acknowledgement of this expectation.[3] Regulatory productivity and efficiency must be prioritised for APVMA to meet Government's expectations.

3.1 Efficiency

AMA members support cost recovery for an efficient regulator on the expectation that the fees charged represent the *minimum efficient cost* to provide that service. The CRP emphasises the importance of efficiency and transparency in a cost recovery arrangement. AMA considers the APVMA may not be fully compliant in its implementation of this CRIS in relation to its calculation of *efficient* costs.

The CRIS has been developed using internal APVMA data from the last 5 years of operations. AMA considers that the past 5 years have demonstrated inefficient regulatory practices and processes. Figures 1 and 2 illustrate declines in the total number of veterinary applications processed and the number of veterinary applications completed within timeframe, especially since 2022-23, against the increase in staffing levels at the regulator. This APVMA data suggests the new fees may be an over-estimate of the efficient costs of completing APVMA's regulatory activities.

[2] Dated 22/12/25. Ministerial Statement of Expectations.pdf
[3] Dated 18/2/26. Regulator Statement of Intent.pdf

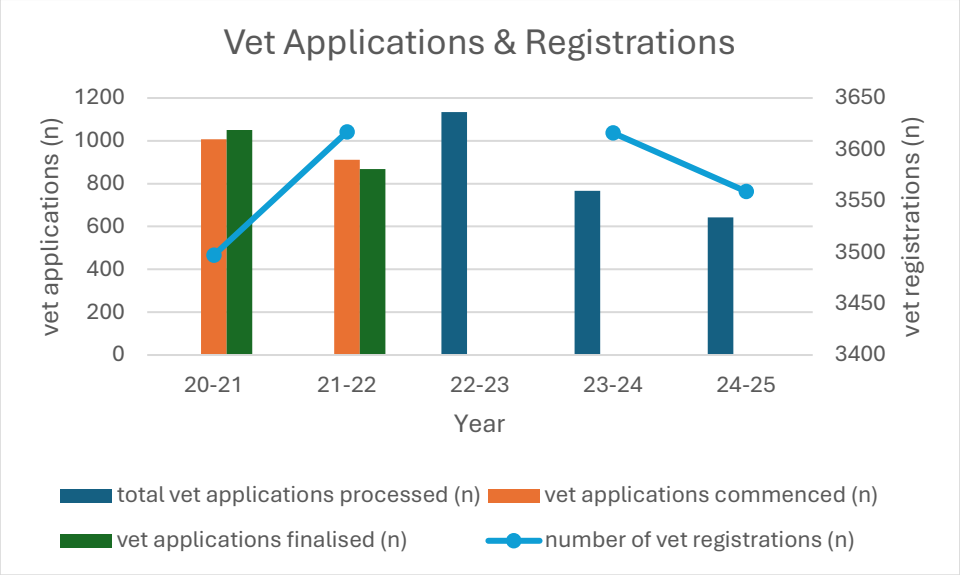

Figure 1. APVMA productivity related to processing of veterinary medicine applications and the total number of veterinary medicines registered (NB: no data available on total number of vet registrations for 2022-23). Data source: APVMA Annual Reports

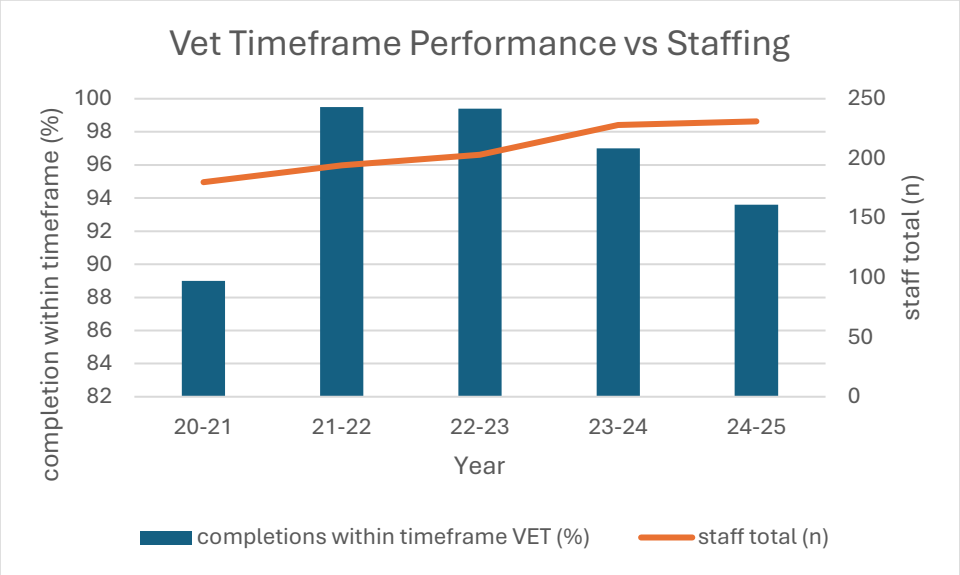

Figure 2. APVMA productivity related to number of staff employed against timeframe performance for veterinary applications. Data source: APVMA Annual Reports

3.2 Transparency

AMA is concerned that despite requests for more detail, there has been no opportunity for AMA or its members to scrutinise the assumptions and workload calculations associated with each application type, which underpins activity-based charging (as noted in the CRP). AMA notes that the comparison of regulatory timeframes alongside the work tasks associated with each application type is central to cost recovery calculations, yet there is no transparency for the regulated community that the timeframes or fees are a true reflection of the relative effort involved, nor evaluate if they represent

the minimum efficient cost, rather than the cost currently incurred, for delivery of those regulatory tasks. The lack of transparency denies industry the opportunity to evaluate if the CRIS represents efficient, necessary and correctly allocated costs. The Government's Cost Recovery Policy explicitly states that "*Nominating costing information as 'commercial-in-confidence' is **not** a sufficient reason for withholding it*" (emphasis added).[4]

The following examples illustrate the lack of information provided in the CRIS consultation documents to justify the proposed fees:

a. Overseas GMP compliance fees

The CRIS indicates that the cost for assessing overseas GMP compliance will be $2,500 per site per year. These fees will generate $1.043m in revenue. AMA understand that APVMA does not undertake any active surveillance of overseas sites and relies on the supply of current GMP certificates to ascertain GMP compliance. The compliance fees collected only from AMA member companies represent sufficient funding for about 7 FTE (based on people costs being 65% of total cost) to carry out this single activity. It is unclear what work this revenue will fund and suggests that manufacturing fees appear to be subsidising other APVMA activities.

b. Changing the holder of a registration (Item 8L application)

An Item 8L application is required to change the holder of a registration. The 2027/28 cost of an Item 8L has been costed at $566 (previously $50). Based on the people cost comprising 65% of this cost, this fee indicates that the registrant will be paying one person at APVMA for more than half a day's work to change a single detail on the registration. This is inefficient in today's commercial environment.

c. Finalisation modules (Modules 11.1, 11.2 and 11.3)

The finalisation modules will all substantially increase in price under the new CRIS. Finalisation 11.1 will go from $8,110 to $22,834. All scientific and technical assessments and decisions have been completed by this point. The magnitude of the finalisation fee implies a considerable amount of work is yet be done at this point but there is no visibility on what that work is or how long it should take to complete efficiently.

d. Item 12 applications

Item 12 is used to process a minor variation to a registered particular or label that does not require any technical assessment. This fee will increase to almost $10,000 (from $2,000). It is unclear how that cost can be justified for a simple variation that requires no specialised assessment.

e. Item 13 applications

Item 13 is used to make a minor change to a registered particular or label that does not require technical assessment, where the change is *required* by the APVMA. This used to be free, but will now cost registrants $2,400. Charging registrants for a task that they did not initiate should be considered as a compliance activity and as such, under the CRP, the costs should be recovered from levies, not fees.

[4] Australian Government Cost Recovery Policy – Australian Government Cost Recovery Policy | Department of Finance, clause 29.

f. Timeframes relative to assessment

Currently, some application types have equivalent assessment timeframes despite requiring less assessment by the APVMA. For example, Items 1, 3 and 4 have 18 month assessment timeframes, and Item 2 is 17 months, yet only Item 1 & 2 require assessment of the active constituent. This indicates a likely mismatch between the work required to be done by APVMA and the allotted timeframe.

The CRP notes that increased fees should only be imposed *after* operational efficiencies have been achieved. AMA is aware that there is significant internal work underway at APVMA to realise operational efficiencies, but notes that some of those efficiencies will take time to flow through the system to deliver meaningful improvements. Whilst AMA is very supportive of this work and looks forward to APVMA returning to a more productive agency, it is inappropriate for registrants to pay substantially higher fees based on the current performance of the agency and which have been calculated based on inefficient regulatory practices.

AMA strongly encourages the APVMA to prioritise the identification of more efficient and less burdensome pathways to delivering its regulatory outcomes. AMA understands that multiple points of duplication, delay and redundancy were identified in the recent Process Enhancement Initiative project. Meaningful efficiency gains may also be identified through a review of administrative regulatory requirements and tasks that consume significant APVMA resources, but do not affect product safety or efficacy.

3.3 Equity

A key intent of the new CRIS framework was to address the inequities and cross-subsidisation of over 6000 current registrations that do not return levies to the APVMA (due to no or very low sales). These 'ghost' registrations will continue to generate zero levy returns but still incur costs for APVMA through post-market monitoring and regulatory overheads. AMA considers that the CRIS will disproportionately impact innovative products and those with small market shares, whilst failing to recover costs from ghost registrations and continuing to require cross-subsidisation of these registrations by levy-paying registrations.

AMA data shows that approximately 80% of registered products return less than $1million in sales annually, yet pay the highest levy rate on those sales. The lowest sales levy rate is applied to the 20% of products which return the highest sales. Under the previous 40/60 fee/levy split, a higher levy on the majority of sales was justified to recover the unpaid costs in a timely manner. However under a full fee upfront model, differentiation of levies is no longer valid. If all applicants will be required to pay full fees upfront in the future (so no registration costs remain to be recovered), then the post-market costs to be funded by sales levies should also be equitable.

The CRIS modelling shows reduced levies across all tiers, but fails to consider the underlying rationale that originally supported different levy tiers. AMA recommends that the tiered levy rates are removed and a uniform levy rate of 0.15% is applied to all registrations.

AMA considers that there are other options to recover assessment costs from ghost registrations that never sell product in Australia, that may avoid the disincentives from large application fee increases.

AMA urges the APVMA to assess the impact of a minimum levy payable for all veterinary medicines. Such an approach will reduce existing cross-subsidies to products with very low or zero annual sales, with no impact on products with levies payable above the minimum level.

This approach may also be time-limited to ensure that minimum levies do not over-recover assessment costs. AMA would also suggest that exemptions are provided for registrations that do not generate levies, but must be maintained for genuine supply-chain, stewardship, contract manufacturing or toll-manufacturing purposes.

3.4 Accountability

AMA notes the absence of mechanisms to incentivise regulator performance and deliver meaningful efficiencies. The CRP only requires APVMA to report on the performance of its cost recovery arrangements, not the efficiency of the work carried out under those arrangements. AMA seeks a stronger focus on regulatory performance and service standards, with greater accountability of the APVMA when its legislated timeframes are not met.

For example, the Veterinary Drugs Directorate in Canada has established a performance standard (timeframe) for each activity. When an application is not completed within the established timeframe, the applicant receives a 25% credit of the fees paid.[5]

In recent years, when struggling to meet their legislated timeframes, the APVMA has chosen to amend its timeframe performance targets from 100% (as required in the legislation) to 90%. This artificially improves the performance statistics but does not incentivise more efficient regulation.

Timeframe performance is critically important to registrants and even small delays by APVMA can lead to significant adverse commercial and animal welfare impacts.

4. Australian Market Considerations

Australia's business operating environment has important ramifications for commercial success. Developing, registering and maintaining a veterinary medicine requires significant investment. When the potential market is relatively small, and fragmented across species and indications, the commercial return may not be sufficient to justify that investment.

The Australian market is small (~2.5% of global sales), which limits the ability of companies to recover the costs of bringing a new product to the market, particularly within short data protection periods. AMA seeks a diverse, innovative Australian industry that supports local research and development, local manufacturing and encourages smaller companies and niche products to enter the marketplace.

Figure 3 shows the 2026 estimated market value for Australia against similar markets in the UK and Canada; Australia is the smallest market. A comparison of registration costs for a novel product requiring efficacy and safety assessment in the same markets shows the opposite trend: even at current fee levels, Australia is the highest cost for registration. Under the new CRIS, Australia's equivalent registration costs will be more than three times higher than in equivalent markets.

[5] cost-recovery-veterinary-drug-submission-evaluation-fees-2019-document.pdf

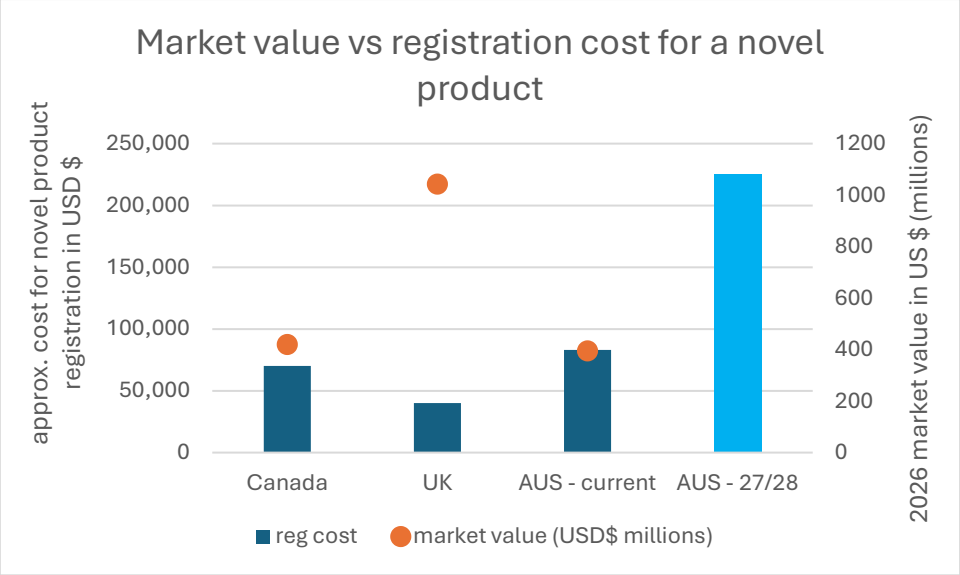

Figure 3. Comparison of 2026 veterinary pharmaceutical market value versus estimated cost to register a novel product (including safety and efficacy).

Data sources:
Australia Veterinary Pharmaceuticals Market Size, Share,Trends, Growth Analysis Report, 2031
UK Veterinary Pharmaceuticals Market Size, Share,Trends, Growth Analysis Report, 2031
Canada Veterinary Pharmaceuticals Market Size, Share,Trends, Growth Analysis Report, 2031

Veterinary medicines are critical inputs to Australia's $46 billion livestock industries that allow producers to prevent and treat disease, undertake necessary animal husbandry and management practices, optimise animal health, improve animal welfare, productivity, profitability, food safety and sustainability. Similarly, veterinary medicines protect and treat Australia's 31.6 million pets from illness, injury and disease with access to safe, affordable veterinary medicines and animal health products. Livestock products account for approximately 43% of market sales at present, while the pet sector represents 57% of the market.[6]

Animal numbers in Australian production systems have been relatively static over the last 5 years at 30-31 million beef cattle, 2.1 million dairy cattle, and 5.8 million pigs. Sheep numbers continue to fall by 2-3 million per year, down to 67 million in 2026. Chickens are the only production species demonstrating consistent, year-on-year increases of 20-30 million birds, to a 2026 total of 752 million.[7] Pet ownership in Australia also continues to grow each year, from 62% of households having a pet in 2016, to 73% of households in 2025, representing more than 31 million animals.[8]

Significant increases to the costs of registering new products will flow on to pet owners and livestock producers through product prices. Advanced diagnostics, veterinary interventions and innovative medicines come with significant costs which pet owners and farmers must bear. A lack of pet insurance coverage in Australia exacerbates the costs of veterinary care for pet owners, and livestock farmers operate with very narrow and unpredictable profit margins, which limits their investment in veterinary medicines even when they could enhance productivity or reduce long-term losses. As veterinary technology advances, and the costs to develop and register new products continues to rise, the

[6] SNR-2403006-Pet-Ownership-Study-2025-Designed_F3.pdf
[7] Animal-Health-Industry-Snapshot-2026_online.pdf
[8] Animal-Health-Industry-Snapshot-2026_online.pdf

affordability gap between available veterinary medicines and consumer financial capability remains an impediment to sector growth.

Veterinary medicines are highly specialised products, targeting specific diseases or conditions in a particular species. This means the market segment for a new product can be very small. Significant upfront fees fundamentally alter the commercial argument to bring a new product to market. Investment decisions rest on the size and structure of the Australian market, upfront costs, risks of market entry, costs of conducting additional Australia-specific trials or satisfying unique Australian regulatory requirements, and lifetime regulatory costs. Decisions to invest in the Australian market are weighed against the costs and potential returns of placing that investment in another market with more efficient and predictable registration, lower post-market levies and stronger post-market incentives. Comparing only the registration fee against the fees charged in other markets significantly underestimates the true cost of bringing a product to the Australian market, especially for products where the business case may already be marginal.

To encourage and support innovation for small segments of a small market, Australia needs a regulatory framework that is affordable, efficient, timely and predictable, with strong proactive compliance activity on illegal and unregistered veterinary medicines, and valuable post-market incentives like data protection. Smaller market share products should also not be disproportionately penalised via higher sales levy rates.

In the absence of changes to the market context, AMA is concerned that diminished incentives for innovative products, alongside small predicted sales, will preclude Australian registration. Several critical actions are needed to provide adequate incentives for companies to invest in registering innovative products and those serving smaller market segments. These include reforms to data protection periods, harmonisation and enforcement of compounding provisions, and incentives to support the registration of niche products.

4.1 Data Protection

AMA recommends the Government increase data protection periods for veterinary medicines to reflect global standards, the increased costs of product development and provide incentives for innovation and investment in the Australian market. Registration of a veterinary medicine and its patterns of use provides the registrant with a period of market exclusivity through the provision of data protection periods. This period is critical to provide adequate commercial returns as well as to support reinvesting in future innovations.

In Australia, new veterinary medicine products including a new active constituent receive 10 years data protection, while new veterinary medicines including an existing active constituent receive just 3 years protection (compared to 5 years for an equivalent crop protection product). As the cost of developing and registering veterinary medicines increases, opportunities to recoup those costs within that three-year period are diminishing – acting as a significant disincentive for registrants to bring products into the Australian market.

Data protection periods for new veterinary medicinal products in competitor markets far exceed data protection periods provided in Australia. In the UK, data protection periods vary from 10 to 18 years, registrants in the EU receive between 10 and 13 years data protection, and registrants in the US receive up to 10 years. Data protection periods should be benchmarked against these competitor markets and offer Australian registrants a minimum period of 10 years for a new product using an existing active and 15 years for a new product using a new active ingredient.

4.2 Compounding

National consistency and enforcement of appropriate compounding provisions is urgently needed to ensure Australia remains an attractive market for new animal health products.

AMA supports the use of compounded veterinary medicines in specific and limited circumstances when a registered product is not available or suitable. Exploitation of the compounding provisions to bulk-produce bespoke medicines under the guise of compounding poses significant animal health risks, directly undermines the integrity of Australia's veterinary medicine regulatory framework and discourages investment and innovation in animal health.

For example, Feline Infectious Peritonitis (FIP) is a serious viral disease in cats that until recently was considered to be fatal, but has now been demonstrated in case studies to respond to a human anti-viral medication. At present, it is only available for use in cats in Australia through compounding. High registration fees under the new CRIS may preclude its registration and this treatment will continue to elude safety and efficacy assessment and monitoring by APVMA.

4.3 Niche Products

AMA seeks initiatives from APVMA to support the registration of niche products where the registration fees may be prohibitively high in comparison to the projected sales. Significant gaps in treatment options exist for both major and minor species, forcing veterinarians to rely on off-label use to provide treatment where available. These gaps can lead to negative impacts on animal health and welfare, agricultural productivity, food security and competitiveness in global markets.

Incentives to support the registration of niche products are vital to building a robust pipeline of new animal health tools for veterinarians, pet owners and livestock producers to fill treatment gaps and address emerging animal health issues. Consideration may be given to strategies such as those used in Canada to support small companies serving niche or low volume markets, where the first pre-market submission is free and fees for subsequent applications are subsidised by 25-50%.[9] Incentives could also be informed by the recently released Office of Minor Use and Minor Species (MUMS) Animal Drug Development (US Centre for Veterinary Medicines) blueprint, which includes extended data protection periods, greater funding of minor use grants, conditional approvals, widening eligibility for MUMS programmes where populations have declined and when development costs are not expected to be recovered from sales within a reasonable timeframe, and increasing operational efficiencies to support veterinary treatments for small markets.[10]

High application fees are likely to encourage companies to prioritise applications with high expected sales volumes and high expected returns, to the detriment of niche products and especially products where demand may be irregular (due to seasonal or episodic disease and pest pressures).

Much of the innovation in veterinary medicines is in niche areas to meet a specific animal health need in a limited market. This includes treatments for chronic conditions in companion animals, such as heart disease, diabetes or cancer, as well as seasonal or episodic disease outbreaks in livestock species. Such products may not sell large, or consistent, quantities each year, but they meet an important animal health need and deliver valuable animal welfare outcomes.

[9] Guidance Document: Fees for the Review of Veterinary Drug Submissions and Applications - Canada.ca
[10] Minor Use and Minor Species (MUMS) Blueprint for Success 2026–2028

Under the draft CRIS, niche products could potentially be pushed into the minor use permits pathway. Permits provide little to no data protection and the approval process is lengthy, requiring similar data to a registration, but providing only a limited period of market authorisation. This provides minimal assurance to registrants, vets and animal owners that such products will remain available long-term.

A lack of registered products also encourages greater use of veterinary compounding provisions, where products are manufactured under lesser quality systems with little-to-no analysis of quality, efficacy, safety, stability or residues. This poses significant risks to animal health and welfare (especially the risks of treatment failure), as well as risks to trade and market access for animal-derived commodities (when compounded products are used in trade species).

4.4 Supporting Australian Innovation

The new cost recovery arrangements dramatically change the business case for innovative products being brought to, or developed in, Australia. Research and development to support innovation spans multiple years, and products currently in development risk being cancelled or delayed while the business case for greater investment is re-evaluated.

Local innovators often invest in filling the gaps for veterinarians between blockbuster products and compounding. Like niche products, the intended market share is small. However, local innovators do not have data packages developed internationally to support registration in Australia and must complete local research to support their application. Australia's data requirements and regulatory standards are already burdensome, and higher upfront fees will disincentivise local innovation.

The new cost recovery arrangements will be more difficult to accommodate for local innovative companies with a small number of products on the market or in development. More established companies may be able to amortise higher registration costs over their portfolio and benefit from lower sales levies. In comparison, local innovators may not have many products currently on the market, where the savings from a reduced sales levy could help to offset higher registration costs.

Permits (in lieu of registrations) are not a viable business strategy as they have similar data requirements to a registration and a lengthy assessment process, to obtain a short period of market approval that subsequently requires renewal to ensure continuity of supply.

Australian innovators have a vital role in the local industry by addressing gaps in treatment options for the benefit of Australian animals. The new CRIS arrangements will favour blockbuster products and compounding, and risk the loss of important new products intended to fill small to medium market gaps in Australia.

4.5 Regulation for the Public Good

AMA considers that the proposed reduced levy rates continue to represent an over-recovery of costs as industry is expected to fund regulatory activities that provide public good services. Many important functions of the APVMA (including post-market surveillance and compliance, chemical review, government reporting obligations and providing policy advice) deliver public goods to support community assurance on the safety and efficacy of chemicals regulated by the APVMA. These activities are essential for robust regulation, but do not provide direct benefit to individual registrants. The clear separation of compliance costs from industry funding would support public understanding and perceptions of APVMA's independence.

AMA considers that the government has a responsibility to provide APVMA with the appropriate and sufficient tools and resources it needs to carry out its legislated responsibilities. AMA considers that targeted government investments in APVMA's infrastructure (such as IT systems) and capabilities (including the provision of in-house auditors) will enable the APVMA to more efficiently administer its regulatory functions and should be publicly funded.

Comparable regulators overseas receive government support to deliver public good services, rather than recovering those costs from their industry. The use of industry funds to provide these regulatory services in Australia is inconsistent with global best practice and perpetuates the misconceptions around industry funding of a government regulator. Stronger government funding of public good services here would serve to more clearly separate regulatory decisions from industry funding and emphasise the independence of APVMA as a science-based regulator.

AMA would welcome discussions with APVMA and DAFF on how the costs of public good activities could be more appropriately distributed between public funding and industry.

5. Opportunities for Greater Regulatory Efficiencies

Improved regulatory efficiency and APVMA productivity is essential under the new cost recovery arrangements. There is a pressing need for APVMA to improve its on-time performance while lowering the unit costs of assessing applications without diminishing regulatory standards. Increased resourcing from industry should be accompanied by greater internal efficiencies and reductions in timeframes.

AMA would strongly encourage APVMA to prioritise operational changes that will deliver clear efficiencies, including process streamlining, the identification of bottlenecks and the removal of duplicative and redundant tasks in internal workflows to deliver timeframe reductions and a return to on-time performance.

5.1 Timeframe Performance

Accuracy in meeting the approval date is equally as important as the overall assessment timeframe. APVMA timeframe performance has been declining over the past 12-18 months, most notably for innovative applications and complex assessments. More recently, even straightforward, administrative applications have also been severely delayed, damaging APVMA's reputation as a predictable and reliable regulator.

Timely and predictable decision making is essential to enable animal health businesses to effectively plan the supply of new products and services and to avoid knock-on effects that cascade delays through product launch plans. Many products for the Australian market are manufactured overseas and their manufacture is booked into tight production schedules timed to a predicted regulatory approval. Missing an approval deadline means a missed production slot, delayed manufacture, and a delayed Australian launch or re-supply. A missed production slot can mean delays far greater than those incurred by a missed approval deadline.

Launching a new product means development and deployment of marketing, sales, training, distribution, supply and education of veterinarians or other users. All of this is planned and cannot commence until approval is received. Even a delay of a few weeks can mean a seasonal window is missed, minimizing the return from that product.

When products are delayed, Australian users are denied access to products that help meet animal health and welfare needs, improve food safety, farm biosecurity and ultimately the productivity of livestock businesses. Delayed access to new animal health innovations puts Australian producers of food and fibre (especially those who export) at a competitive disadvantage when compared to other markets that deliver timely, predictable approvals.

5.2 Reducing Timeframes

AMA seeks genuine streamlining of regulatory processes that deliver timeframe savings for both applicants and assessors. Previous efforts to improve efficiencies have 'tinkered at the edges' and have not delivered meaningful improvements to registrants. The recent Process Enhancement Initiative project has apparently improved operational efficiencies internally, but has not delivered discernible improvements from the applicant perspective.

Reductions in timeframes deliver benefits to industry by getting products to market sooner, generating income that can offset high registration costs and be re-directed into research and development for future products. For example, a three-month reduction in assessment timeframe on a new product that is expected to deliver $1m in annual sales could be worth $250,000 to the applicant.

Increased fees would be more justifiable if all assessment timeframes were reduced by 25%.

A number of application types used to manage minor and non-technical variations to registrations are disproportionately long compared to the work required to assess. This includes application types that do not require technical assessment or the provision of data, such as Item 12 and 13 (both 3 month timeframes).

AMA members also note that there are opportunities to deliver timeframe improvements through more effective use of international data and technical assessments. Although the ability to include international data in APVMA applications has improved, it has not delivered the expected timeframe savings or reductions in administrative burden. AMA considers that APVMA could deliver efficiencies through greater emphasis on the assessment of any Australia-specific data requirements or unique risks that may be posed with use in the Australian context, rather than repeating the technical assessments of other equivalent, trusted overseas regulators. AMA expects that the new agreement with the New Zealand regulator, and tri-lateral assessments with Canada, will provide confidence for the APVMA to engage with other equivalent regulators for mutual benefit.

5.3 Registration Management

The new CRIS will impose considerable fees on registrants who seek to keep their registrations up to date via Notifiable Variations (NV) and applications under sections 8L, 8M and 8P of the Agvet Code.

Important operational efficiencies could be realised by taking a more risk-proportionate approach to variations. There are many inconsequential updates to registrations that could be more efficiently managed by registrants rather than APVMA without posing a risk to product safety, efficacy or trade. Applicants could be required to inform APVMA of any relevant changes on a periodic basis (eg: annual reporting) rather than requiring a section 8 or NV application for each individual change. Such permitted changes could include:

- Correcting minor label errors including spelling errors
- Label re-formatting to align with current VLC requirements, such as:

  - relocating statements on a label (without altering the statement itself) to align with the VLC eg: moving statements from 'Dosage and Administration' to 'General Directions' where appropriate.
  - Reformatting WHP statements to put each statement on a separate line
  - Reformatting WHP statements from "Milk-nil" to "Milk – Zero (0) days"
  - Replacing "DO NOT USE" statements with "NOT TO BE USED"
- Deleting an active constituent supplier from an approval or a manufacturing site from a registration.
- Replace outdated scientific names with current ones eg: *Boophilus microplus* to *Rhipicephalus australis*, or correct misspelled scientific names.
- Update 10A secondary labels to reflect primary label changes.
- Amend or correct the name of an excipient where the CAS number is unchanged
- Amend the abbreviation of the product name as it appears throughout the text label

5.4 Minor Changes

The use of applications to manage minor changes is disproportionate to the risks posed by those changes. Changes that do not require technical assessment should be more appropriately managed via Notifiable Variations (NV) instead of requiring an Item 12 application (variation to make a minor change where no technical data is required). Similarly, modular applications to make a non-technical change will become exceedingly expensive when combined with the mandatory Preliminary Assessment and Finalisation fees, on top of the shortest modular assessment fee.

For example: minimum costs and timeframes for a non-technical variation:

Item 12	**3 months**	**$9941**	(393% increase from 2026/27)
Modular	**4 months**	**$7,856**	
Preliminary Assessment		$2,480	
Chemistry 2.5		$1,012	(non-technical assessment module)
Finalisation 11.3 (min.)		$4,364	

At present, changes that are not related to registered particulars can be made without application, provided the registrant is satisfied that there will be no impact to product safety, efficacy or trade criteria. However there is no formal mechanism to submit such changes to the APVMA to allow updating of APVMA records, creating compliance issues for both the regulator and the registrant. Enabling submission via the NV pathway would make these changes to Records and the Register much easier to track and would also align the APVMA with the 30-day 'do-and-tell' process used by most overseas regulators for such changes.

AMA recommends that non-technical variations be removed from the cost recovery framework and the obligation placed on registrants to inform APVMA of any changes (in the same way that section 161 of the Agvet Code requires registrants to notify APVMA of relevant new information). This would reduce the workload and create considerable cost savings for APVMA without posing unacceptable risks to product safety, efficacy or trade.

For example, if 75% of the Item 12 applications expected in 2027/28 were instead processed as NVs, a cost savings of $1.2m for APVMA could be realised (Table 1).

	CRIS 2027/28: expected completions (n)	CRIS Estimated Cost 2027/28 ($)	If 75% of Item 12 became NVs: expected completions (n)	New Estimated Cost 2027/28 ($)
Item 12	171	1,699,911	171 – 128 = 43	427,463
NV	169	95,654	169 + 128 = 297	168,102
TOTAL		1,795,565		595,565
SAVING		**1,200,000**		

Table 1. Estimated savings if 75% of expected Item 12s were processed as Notifiable Variations.

5.5 Guidance Materials

AMA considers that improvements in guidance materials could have a significant impact on regulatory efficiency by reducing effort spent by the APVMA and applicants on applications that may not meet the criteria for approval. Guidance is essential to facilitate consistent understanding of regulatory requirements by both the applicants and the regulator. The efficiency costs arising from inadequate guidance should not be borne by industry.

AMA notes that almost $3million is noted in Table 4 of the CRIS for the 'provision of guidance'. This is a substantial budget item but there is no further information provided on what may be delivered with this activity. It is also not clear whether this is to be funded by appropriations or from levies (the table claims to, but does not, present that information). AMA expects that this activity should be funded by appropriations as it is an integral element of the core regulatory framework, where the provision of guidance is essential to allow users to interact with the regulatory system in order to meet their legal obligations and obtain market access.

APVMA may wish to consider:

- publishing (in a de-identified and confidential manner) information on frequent issues and trends where applicants have not met APVMA's contemporary assessment requirements. This would include issues identified in PAAs as well as applications.
- providing clear guidance materials to clarify expectations, improve application quality, reduce reliance on PAAs to determine application requirements, and ensure mutual understanding by both regulatory staff and applicants. This includes revision of existing guidance (such as for active ingredient approvals) and the creation of new guidance where none currently exists (such as for chemistry and manufacturing changes, antibiotics or expectations regarding documentation for non-assessable changes).
- developing a clear and consistent regulatory approach to emerging technologies (such as nanomaterials, monoclonal antibodies, hemp and cannabis products, and methane inhibitors) that is aligned with global approaches to such products.
- developing internal guidance and processes to streamline workflows and improve consistency in decision-making by APVMA staff.
- greater alignment of APVMA requirements with international standards and guidelines (such as VICH guidelines) and more efficient use of international data and technical assessments completed by equivalent trusted regulators.

6. Recommendations for Implementation

AMA's priority is to minimise the negative impacts of implementation of the new CRIS. AMA recommends that the APVMA:

6.1 Phase-in new fees over a three-year period.
6.2 Stagger payments across the assessment timeframe.
6.3 Ensure that any fee changes are confirmed at least 12 months prior to implementation.
6.4 Remove the levy tiers and reduce the sales levy to 0.15% for all products.
6.5 Provide incentives for niche products
6.6 Support Australian innovation

AMA notes that partial cost recovery arrangements when new charges are being 'phased in' are consistent with the Government Cost Recovery policy.

These measures will assist registrants to manage the commercial implications of the new cost recovery arrangements in a more equitable manner and spread the expected application surge over a longer transition period, whilst still moving APVMA towards the new funding model over a defined period.

6.1 Phase-in new fees over 3 years

AMA recommends that the APVMA implement the new fee structure over a 3 year period. Smaller fee increases more frequently are easier to handle in a commercial setting than larger changes infrequently. For example:

Current fees - 40% of full fees
Year 1 – increase fees to 60% of full fee
Year 2 – increase fees to 80% of full fee
Year 3+ – 100% upfront fee recovery

The planned implementation date of 1 July 2027 gives companies less than 12 months to prepare for substantial increases in registration fees, which poses risks to business continuity and innovation agendas that are already underway. Annual budgets for registrants are often set more than one year in advance and the budgets for 2027-28 have already been confirmed. AMA member companies include the local subsidiaries of major international companies with global operations and headquarters based overseas. They may be required to operate on internal budget cycles that do not align with the Australian financial year and have limited flexibility to make significant changes in their financial forecasts at short notice.

Significant fee changes are also disproportionately harder to manage for companies with smaller product portfolios and for products where the projected sales may be limited (including niche products, minor uses or minor species).

The registration pipeline within companies spans multiple years and is supported by transparency and predictability of expected registration fees. Considerable increases in fees with minimal lead-in time poses genuine risks of new products being removed from the registration pipeline. Phasing in new fees over a three-year period will assist industry to plan and manage the transition to a new cost recovery framework.

6.2 Incremental payment of fees across assessment timeframe

AMA recommends that payment of the new fees is staggered across the application timeframe to approximate the work APVMA completes in that time. For example, for an 18month assessment timeframe:

- 30% payable at application submission (t=0)
- 30% payable at mid-point of assessment timeframe (t=9 months)
- 40% payable when application is finalised (t=18 months).

The increments would be scheduled according to the application timeframe and not associated with the completion of specific assessments. The final increment would be payable on finalisation of the application.

Incremental payments may not be appropriate for applications with timeframes of less than 3 months.

6.3 Confirm fee changes at least 12 months in advance

AMA would encourage APVMA to finalise any annual fee changes a *minimum* of 12 calendar months from the intended date of implementation. Regulatory budgets are generally set 12-18 (or more) months in advance, and operational commitments for companies to register new products span multiple budget cycles (years). Minimal lead-in times and significant changes to projected regulatory expenditure may result in delays to planned market entry and loss of product availability.

6.4 Remove the levy tiers, reduce the sales levy and consider a minimum levy payable for all products.

AMA recommends that the levy tiers are removed, that a reduced sales levy of 0.15% is applied to all registrations and a minimum levy payable is established. If all registrants will be required to pay full fees upfront under the new CRIS, there is no longer a justification for the sales levy to be tiered and the same levy should be recovered from all registrations. Continuation of a tiered levy structure is inconsistent with a full fee upfront approach to cost recovery and will unfairly penalise products with small market share. A minimum levy payable would help to address ongoing cross-subsidisation of ghost registrations, with no impact on products with levies payable above the minimum level.

6.5 Incentives for niche products

AMA requests that APVMA consider registration pathways for products that may not meet commercial expectations for full registration, but also do not meet the criteria for minor use permits. These products address important treatment gaps and provide valuable animal health and welfare outcomes.

AMA would encourage APVMA to consider the use of partial fee waivers as prescribed in section164 of the Agvet Code Act[11] to support the registration of niche products. These could include new products for smaller livestock sectors such as sheep, which are considered a major species in Australia, but a minor species in most other countries. Innovation in sheep products is heavily influenced by the Australian sheep industry, which then filters to other markets worldwide. If new sheep products were unable to registered in Australia, the global sheep industry will also lose those innovations.

[11] Agricultural and Veterinary Chemicals Code Act 1994 - Federal Register of Legislation

6.6 Supporting Australian innovation

Local innovators often invest in filling the gaps for veterinarians between blockbuster products and compounding. Like niche products, the intended market share may be small.

AMA recommends that APVMA and DAFF consider incentives to support local research, development and innovation, especially improved data protection and stronger compliance activity on illegal and unregistered veterinary medicines.

AMA would encourage APVMA to consider the use of partial fee waivers as prescribed in section164 of the Agvet Code Act[12] to support the registration of local innovations for small market segments.

7. Conclusion

AMA supports APVMA to be appropriately funded in order to carry out its legislative obligations and responsibilities efficiently and reliably. Our industry agrees to contribute to an efficient and effective regulatory system that is predictable, consistent, transparent and equitable.

Whilst supportive of the move to full upfront fee recovery, AMA has concerns related to the implementation of this CRIS, particularly given current APVMA performance, and the adverse implications this may have on innovation and the attractiveness of the Australian market for new veterinary medicines.

The lack of transparency on the calculations underpinning the CRIS is concerning and provides little assurance of accuracy of the CRIS calculations, nor confidence that substantial increases in industry's contribution to the APVMA's budget will have a positive impact on regulatory efficiency, predictability or outcomes.

The business environment for veterinary medicines is a critical factor in the decision to bring a product to Australia. The lack of adequate data protection and the exploitation of compounding provisions currently acts as a significant disincentive to register products in Australia. Improved data protection and more consistent regulation of compounding provide important commercial incentives for companies to invest in Australia and its animals.

The new CRIS is being proposed during a period of historically poor performance by the regulator and it is difficult to justify substantial fee increases at this time. The principle of cost recovery is to fund *efficient* regulation and AMA seeks to ensure that a substantial increase in contributions from industry will result in performance and productivity improvements at the APVMA that will allow it to deliver its regulatory outcomes more efficiently.

It is AMA's expectation, given the transition to full upfront cost recovery arrangements for the evaluation and management of regulatory submissions, that APVMA now prioritises the establishment of the resources required to consistently meet their legislated timeframe commitments and confirms that these resources will not be seconded from application assessment to unrelated activities.

[12] Agricultural and Veterinary Chemicals Code Act 1994 - Federal Register of Legislation