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Mr Andrew Heath
Director, Strategy and Governance
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
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By email only: enquiries@apvma.gov.au

Dear Mr Heath,

Re: APVMA Strategic Plan 2025-30

Thank you for the opportunity to provide feedback on the new Strategic Plan ('the Plan') for 2025-30.

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 member companies are global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent approximately 80% of registered veterinary medicine sales in Australia.

AMA and its members have a long-standing commitment to an animal health industry that is responsible and sustainable. Our members' products are essential tools that can help meet economic, environmental and social challenges.

Animal health products are critical inputs to Australia's livestock production systems and protect our companion animals, wildlife and exotic species. Having ready access to the tools necessary to keep animals healthy is key to a productive, sustainable and resilient society in Australia, with subsequent environmental, economic and social benefits. It is vital that Australian farmers and pet owners have timely access to the critically important animal health products that AMA's member companies provide.

The Australian market for veterinary medicines is approximately 2-2.5% of global sales and compared to market size, the regulatory costs are significant. AMA seeks to ensure that the regulatory environment for veterinary medicines in Australia is robust, proportionate, effective, efficient, fit for purpose, risk-based and scientifically sound. and consistent with government principles of best practice regulation.[1] APVMA's regulation of veterinary medicines should align with globally accepted standards and requirements wherever possible to support investment and innovation in the Australian market.

AMA is pleased to provide the following comments on the draft Strategic Plan 2025-2030. AMA also acknowledges the submissions made by the National Farmers Federation and the Australian Veterinary Association with respect to veterinary medicines.

APVMA's purpose

In principle, AMA supports the purpose of the APVMA as noted in the Plan. However AMA considers that this statement should closely align with and reflect the full statutory purpose for the APVMA as specified in the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code). The APVMA's purpose should recognise the necessity of agricultural chemicals and veterinary medicines as critical inputs to Australia's agricultural and pet sectors through policies and regulatory approaches that:

-are based on scientific evidence and risk assessment,

- provide timely and efficient access to new agricultural and veterinary technologies,

- encourage global trade of Australian-produced agricultural commodities,

- support domestic manufacturing, and

- reflect the principles of cost effectiveness, efficiency, predictability, adaptability and responsiveness.

Strategic objectives

AMA supports the 5 pillars identified in the Plan to guide APVMA's priorities and performance.

Being a trusted, transparent and fair regulator

AMA supports this pillar. AMA and its members consider that predictability (in both data requirements and in timeframes) is key to achieving this objective. The development of a new veterinary medicine is a significant undertaking for companies and establishing the APVMA's data requirements early in the development process is critical to success. Launching a product in a market is a similarly significant undertaking. Having a predictable outcome in terms of an approval date and label will drive investment in the Australian market.

[1] Home | The Office of Impact Analysis

Transparency is central to being a trusted regulator. Transparency in requirements, processes, responsibilities, communications and personnel should be prioritised across all APVMA functions and levels. In particular, transparency in decision-making is essential. To the greatest extent possible, decisions should be scientifically justified, based on risk assessment, consistent with internationally-respected guidelines and standards, and respect outcomes determined by previous APVMA assessments, as well as those of equivalent overseas regulators. APVMA should ensure that the process by which decisions are made, and the reasoning for any decision, is transparent to stakeholders.

Potential measures

Measure 1 *"The proportion of stakeholders surveyed who agree that the APVMA has been a trusted, transparent and fair regulator over the past 12 months"*

- AMA supports this measure in principle, but notes that 'stakeholders' are not a homogeneous group and will have different interactions with the APVMA. Registrants may have different views and expectations of their interactions with APVMA compared to end-users, just as the users of veterinary medicines have different views and expectations to the users of agricultural chemicals. Consideration of different stakeholder categories will ensure that this measure can appropriately assess the intended outcome and reveal particular areas for improvement.
- A measure of the quality of APVMA's risk management and decision-making would be helpful to demonstrate stakeholders trust in the APVMA and its processes.

Measure 2 "*The proportion of all applications finalised within legislative timeframes"*

- Timely, predictable decision-making is critical for registrants. Timeframe performance reflects the capacity of APVMA to complete its required tasks in a timely and efficient manner; it does not equate to scientific rigour nor represent trust in the scientific assessments or decisions made. The timeframe performance measure should be close to the legislated target but, as recognised by Clayton Utz, it is not the only measure.
- AMA notes that Item 27 applications may need to be considered separately, as timeshift project plans set timelines that may be amended during assessment and which may not correlate with legislated timeframes. These applications will not be captured by this measure.

Measure 3 *"The number of Proposed Regulatory Decisions and Final Regulatory Decisions for chemical reconsiderations that are released within the reporting period"*

- AMA sees potential risk in adopting this performance measure. All reconsiderations must be science and risk-based, and should not be determined by an arbitrary timeline. The necessary work for a reconsideration should determine the timeline; it cannot be determined in advance. Some reconsiderations will be straightforward, whilst others will require much more complex consideration, the generation of new data and risk management assessment. These decisions should not be rushed and must consider all relevant data. The timelines for these decisions should be appropriate to the complexity of the reconsideration.
- Recent Ministerial directions to conclude a number of long-standing Chemical Reconsideration processes imposed significant resource demands that the APVMA was

under-resourced to meet, leading to considerable redeployment of APVMA staff at the expense of other essential regulatory activities, leading to declines in timeframe performance (a separate performance measure). Sacrificing performance in one area to improve performance in another area is undesirable and likely indicates under-resourcing of the APVMA to complete its required tasks.

Measure 4 *"The proportion of serious adverse experience reports received and assessed by the APVMA within 20 business days"*

- AMA suggests that this measure is rephrased to more clearly articulate the desired outcome: "The proportion of serious adverse experience reports that are assessed within 20 business days of being received".

Support a contemporary regulatory system

AMA supports this objective, including a renewed focus on compliance and enforcement activities. A contemporary regulatory system would use a risk-based management process to regulate products, have efficient and effective regulatory processes, reduce regulatory burden where possible, seek to use contemporary regulatory and scientific thought to guide its processes and decisions, and include a process of continuous improvement. AMA would encourage the APVMA to consider alternative performance measures that would reflect these issues more clearly.

AMA supports greater engagement and strengthening relationships with state authorities – this is needed. Better engagement with state and territory authorities will promote a more cohesive, consistent and effective regulatory approach across jurisdictions.

Efforts to move towards greater acceptance of overseas assessments are welcomed by AMA members. Registrants note that greater guidance from APVMA is needed in this area to realise greater efficiencies with the use of international assessments. At present, the time savings potentially available with the use of international data are outweighed by the time taken to complete the mandatory Pre-Application Assistance process.

Potential measures

Measure 5 "*The number of compliance activities, recalls and/or other regulatory actions the APVMA undertakes, including those with State and Territory partners"*

- The utility of this metric is unclear – a simple count of compliance activities does not reflect the need for those activities or the risk posed from non-compliance. In order to confer trust in the regulatory system, the reporting of compliance activities must be accompanied by information about the *reason* for those activities. In the absence of context, a high count of compliance activity will be mis-interpreted as indicative of 'problems' in the system by those with an agenda or, conversely, a low number will be interpreted as inactivity by the regulator.
- Compliance outcomes are more important than the level of activity. Success in this area could be indicated by a reduction in the need for specific compliance activities associated with (for example) advertising, labelling or manufacturing.

Measure 6 "*The number of submissions, proposals or other significant contributions the APVMA makes at domestic or international fora"*

- This measure will support greater transparency on APVMA's engagement with other regulators and its position on domestic regulatory issues. APVMA's engagement with the international regulatory community is vital to support global harmonisation of technical requirements and encourage contemporary methods, standards and knowledge to be implemented here.

Measure 7 "*The cumulative amount of time saved in application assessments by using international assessments"*

- Better use of international assessments to deliver time savings would be welcomed by AMA members. Further efficiencies would be possible with greater acceptance of international data formats accepted and used by other equivalent regulators, so that international dossier modules can be more readily used with minimal reformatting or amendment.

Building foresight capability

AMA supports this objective. Building *effective* foresight capacity is reliant on the ability of APVMA to be flexible, adaptable and responsive in order to regulate new technologies, or regulate in new ways, as needs arise. Building the scientific and regulatory expertise within the APVMA, as well as connections with industry experts and other regulators, is critical to support a resilient, forward-looking and contemporary regulatory agency.

Previous attempts to prepare for new technologies have not yet delivered results. For example, nanotechnology was a major focus for several years, but those efforts have not been reflected in the number of applications seeking to register products using that technology. Acting too soon on emerging issues risks resource diversion to areas that may not develop as anticipated.

It may be more effective for APVMA to focus its limited resources on localising the extensive work already being conducted on various emerging technologies and issues by the FDA and EMA.

AMA would encourage closer engagement with industry to evaluate emerging issues, identify priorities and support resources being directed to topics of genuine need. It would also be useful to take a broader view of potential issues rather than focusing on emerging technologies. For example, travel bans during the COVID pandemic severely disrupted GMP inspection schedules, leading to an unexpected need for alternative remote audit models in order to maintain product supply. Supply chain disruptions for packaging materials or key ingredients can similarly generate a sudden need for rapid assessment and approval of alternative packaging or sources, with little advance warning. APVMA's ability to respond to emerging and unexpected issues, as well as emerging technologies, is vital.

Potential measures

Measure 8 *"The proportion of stakeholders surveyed who believe the APVMA has effective foresight capability"*

- Similar to Measure 1, AMA considers that this measure would be improved by grouping 'stakeholders' (registrants, end-users, regulators, veterinary medicines, agricultural

chemicals), as the perspectives and expectations of stakeholders will vary by sector and influence their assessment of APVMA's foresight capability.

Measure 9 "*The proportion of externally validated evaluations of the APVMA's scientific capability that pass quality and performance criteria"*

- AMA supports this measure in principle, but further detail on the methodology, and the quality and performance criteria to be used, is required to assess the quality and utility of this measure.

Measure 10 "*The number of guidance documents, discussion papers etc that the APVMA contributes to, writes or presents at domestic and international fora"*

- AMA supports this in principle, but notes that the proposed measure is a simple count of documents, rather than an assessment of the quality or utility of those documents. Guidance documents are vital for registrants to guide dossier development and ensure that applications submitted are complete, correct, and contain all required information. It is important that this reporting measure does not result in the development of documents that do not meet stakeholder needs in order to boost reporting numbers.
- The value of APVMA activity in this area is directly related to the quality, clarity and outcomes that may result. Quality-based metrics such as scientific robustness, clarity, consistency and stakeholder confidence, would be more informative than a quantity metric and provide a greater indication of the APVMA's true performance and contribution to science-based regulation in Australia and abroad.
- AMA supports greater transparency on the production of discussion papers that indicate APVMA's position on emerging issues and technologies, and its engagement with the local and international regulatory community. This will assist in the development of guidance and standards that accommodate Australia's needs, thereby supporting the adoption of globally-consistent technical requirements and standards by APVMA. Again, the usefulness of this measure will depend on whether the count of documents is accompanied by greater transparency on the content of those documents.

Striving for operational excellence

AMA supports this objective. There is potential for greater efficiencies to be realised through operational changes, streamlining of internal processes and improving APVMA's ICT capabilities. AMA is pleased to note the progress already made this year on the process mapping initiative; this will be an important foundation for making meaningful operational improvements.

This objective would be well served by consideration of the alignment between assessment timeframes and actual resource requirements. This is problematic for Chemistry assessments in particular, where s159 notices are routinely issued. The questions being asked can often be answered by the applicant and assessed by the APVMA within a matter of days, but use of the s159 notice mechanism adds months to the assessment timeframe.

There are considerable efficiencies to be gained through improvements to routine administrative tasks, a number of which result from outdated ICT and data management systems. For example:

- the inability to provide registrants with a list of their own overseas manufacturing sites on annual compliance fee invoices leads to significant additional work for both the regulator and registrant to ensure the invoiced fee is accurate.
- The annual levy declaration system requires registrants to enter sales figures manually into a website that does not allow a copy to be downloaded for offline review. Particularly for larger companies, this is a significant data entry task that must be done without error and without the ability for anyone else to review before submission. The resultant levies based on this data entry are substantial and are audited by APVMA, so accuracy is critical. Digital data transfer would confer significant improvements in accuracy and reduce administrative burden.

Potential measures

Measure 11 "*The APVMA Regulatory Achievement Score is at or above the target"*

- AMA supports this measure in principle. The three elements of the proposed composite measure are all valid, but the usefulness of combining them to produce a single metric is unclear. Composite measures can easily be skewed and are not necessarily reflective of ongoing, consistent standards of performance. However the three elements used as separate measures could be informative in providing an overall indication of performance across all areas of responsibility.

Measure 12 "*Milestones outlined the APVMA ICT investment plan are delivered on time and on budget"*

- AMA supports this measure, but notes that there has previously been significant expenditure and resourcing from both APVMA and the regulated industry towards ICT improvements over the last 5 years with negligible benefit. The need for improved ICT infrastructure is clear and unquestioned, but how this could be achieved must be critically examined in collaboration with industry to ensure genuine progress is achieved.

Attracting, developing and retaining talented people

AMA supports this objective, as staff turnover is a significant risk for APVMA. Chemical regulation is a highly specialised area and it takes time for new staff to become proficient in their roles and have the confidence to make decisions.

Improvements in handover procedures would also assist in ensuring applications in progress do not get overlooked or lost.

Potential measures

Measure 13 "*Proportion of APVMA staff who report a high level of engagement with the APVMA"*

- This measure is supported.

Measure 14 "*APVMA Expert Scientific Reviewer (ESR) Investment Score is at or above target"*

- AMA supports the use of External Scientific Reviewers, where appropriate, to support APVMA capability and ensure efficient scientific assessments by appropriately qualified experts.
- AMA does not have a position on the appropriateness of the proposed composite measure to accurately assess or monitor ESR investment, but it seems reasonable in the context. However AMA expects that success will be strongly related to communication between applicants and ESRs, and how effectively they can exchange information with each other. Delays can occur when ESRs must request clarifications through APVMA Case Managers, adding at least one administrative hand-off to every query. Direct dialogue lets the applicants supply data and study reports or rationales in real time. Likewise, reviewers can test preliminary interpretations with applicants, resolve methodological questions and ensure that data packages address guideline requirements before finalising the draft. Good communication supports the reviewer to maintain momentum and complete assessments on time.

Measuring Performance

AMA is pleased to provide the following comments in addition to those on the proposed performance measures in our submission.

Performance metrics are an important element of transparency between a regulator and the regulated community. Bringing a new product to the Australian market is an expensive and time-consuming process. It is therefore vital that the regulator is able to deliver scientific and regulatory decisions in predictable and reliable timeframes to support commercial investment in the Australian market.

Some suggestions for other potential performance metrics are as follows:

1. Reporting of key metrics by assessment area. This would be particularly helpful to identify bottlenecks and areas where important efficiencies could be realised.
2. The number of applications receiving s159 notices.
3. Average time for overdue applications. The current 'average time by Item number' presumably includes both within timeframe and overdue applications. It would be helpful to know that once an application is overdue, *how* overdue it may go.
4. For Item 27 (timeshift), the due dates can be changed whilst the application is in progress to accommodate changes in the project plan. However this could also be done to avoid applications falling overdue. A measure of how often the due date is changed, and whether it is changed by APVMA request or applicant request, would clarify that this mechanism is being used as intended.

Whilst the current performance metrics are useful for registrants and industry stakeholders, the addition of a number of proposed measures in the Plan would contribute to a more comprehensive and nuanced assessment of agency performance. However AMA members would not want to see significant resources diverted from daily operations to generate a substantial number of new performance metrics.

Thank you for your consideration. Please feel free to contact me if you have any questions or would like further information on any point.

Yours sincerely,

Dr Charmian Bennett

Director Science and Policy