REASON GROUP

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Independent Review of Assessment Performance

REPORT SUMMARY

AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY

FINAL

22 DECEMBER 2017

BUSINESS PERFORMANCE SPECIALISTS

Sponsorship

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EXECUTIVE SUMMARY

Independent Review

Reason Group undertook an independent review of the Australian Pesticides and Veterinary Medicines Authority's (APVMA's) assessment performance. Data was analysed and interviews undertaken with key personnel. The observations and opportunities were determined based on these interviews, research and data analysis from the APVMA's own portal. Recommendations were developed to assist the APVMA improve performance of agricultural and veterinary (agvet) chemical assessment and registration activities.

KPI Reporting

APVMA assessment timeframes are statutory and a target of 100% is expected, however, APVMA has rarely met this target. Public and industry interest in the APVMA's performance is overwhelming, with much commentary surrounding each quarterly report. Since the implementation of reforms in 2014, a number of reports have been commissioned to review specific subsets of APVMA assessment performance and to identify areas for improvement. Internationally, similar agencies are also challenged in meeting their performance targets in an environment of increasing assessment complexity. These agencies have undertaken a variety of reforms.

Reforms to Improve APVMA Performance

Reform of APVMA assessment performance largely depends on changing how the organisation responds to poor quality submissions (notably responses to non-frequent applicants) and changes to assessment processes (which may require regulatory support). There are a number of initiatives underway at the APVMA that will support the improvement of assessment timeframes and make it easier for industry to submit better quality applications. These initiatives have been listed alongside the detailed recommendations developed in this report and include improvement to APVMA guidance documentation as well as the development of ICT systems to better support assessment workflow and reporting.

OBSERVATIONS

- Ability to report timeframe performance to Parliament is at risk due to the manual process undertaken each quarter. Currently the business systems within the APVMA do not support dashboard reporting. Extensive effort is required to undertake specific reports on assessment times and status. Engagement showed APVMA ICT systems lack organisation-wide workload management capability and application status reporting, which could inform priorities and provide better visibility of assessment activities, overdues, client history and other indicators
- The top 38 applicants account for over 50% of the assessments, there are over 800 applicants that make up the remaining assessments. More frequent applicants tend to have their applications assessed within legislated timeframes and are higher quality applications. This results in the Authority assisting industry beyond what legislators anticipated, when timeframes were set. The additional effort contributes to the APVMA's unsustainable operational losses and unmet targets
- The large backlog of overdue or on-hold applications diverts significant resources away from new applications. There is no incentive to complete overdue applications. The APVMA has recently made gains in the assessment time of some items by focussing on backlog reduction and improving resourcing
- Recategorisation occurs when clients submit a product for registration as one item, or assessment level, and then it is recategorised to another. Currently recategorisation of applications occurs late in the evaluation process, resulting in less time being available for the technical assessment. Recategorised assessments contribute significantly to unmet performance targets
- Guidance material and legislation is applied in a very prescriptive manner, rather than applying the objectives of the Act (which would allow for flexibility in the application of the modules). For example, the APVMA required four days to determine whether dog toothpaste should be registered
- Previous decisions and conservative legal advice have resulted in a low appetite for risk across the organisation. The delegation level required to approve and finalise registration has been raised, increasing the time to complete assessments. There are also inconsistencies in how assessors summarise and approve their module assessments, with some delegates having to read the whole report and revise the summary findings, before approving

EXECUTIVE SUMMARY CONTINUED

Analysis of International Regulatory Agencies

It is difficult to directly compare performance of regulatory bodies due to the different regulatory systems, fee structures and levels of scientific rigour in place. While comparison across jurisdictions is difficult, there is evidence to suggest that the performance issues being experienced by the APVMA are also challenging for other international regulatory bodies. No other registration system we reviewed reports its performance as frequently as Australia. The published quarterly performance statistics are a commitment made by the APVMA as part of the Australian Government's Regulator Performance Framework (sections 5.1.a and 5.1.b). These performance metrics are developed through consultation with industry and agreed by the Minister. The Canadian Veterinary Drugs Directorate (VDD) reports average time taken to process applications. This may be a more representative way of reporting regulatory system performance, as it reduces the effect low quality and complex applications have on statistics.

Increasing Assessment Complexity

An increase in assessment complexity over the last five years has been reported by international counterparts and confirmed by APVMA assessors. For example, at the APVMA, the mean Residue Complexity Index (ROCI) almost doubled between 2009 and 2016. This demonstrates that the type of residue assessments now being undertaken by the APVMA, require more time and expertise than they did in 2009. Some regulators charge for actual time taken to process applications, unlike the APVMA's fixed fees which do not allow for increasing complexity and assessment effort. Technical completeness reviews of data prior to the acceptance of the application (when the regulatory clock starts) is also common internationally, however not currently utilised by the APVMA. Australia is also the only registration system we reviewed in which regulatory clocks do not stop, whilst awaiting information from the applicant.

The Use of External Scientific Services

The use of third parties, with peer review and approval by the regulator, has provided efficiencies for international agencies. Efficiencies have also been gained through the acceptance of assessments performed by other regulators and joint initiatives between free trade agreement partners.

RECOMMENDATIONS

Improve the use of regulatory instruments:

- Empower and train APVMA assessors and risk managers in the application of the legislation and regulatory guidelines. Legal officers to provide lessons learned and feedback to staff from overturned decisions
- Encourage quality applications through better use of refusals and requests for information. Refuse poor quality applications through the use of existing provisions of the Act (8S and 8G)
- Develop a more efficient model for using external scientific services
- Provide a list of regulatory consultants to low frequency clients and strongly encourage applicants to use regulatory consultants when submitting applications that require modular assessments
- Strongly recommend Pre-Application Assistance (PAA) for modular items, like item 10 assessments, to reduce recategorisations
- Implement a risk return model for processing of applications where high quality/lower risk applicants are expedited through the assessment process

Build more efficient processes for assessments:

- Restructure resources to address the backlog of overdue assessments
- Allocate resources early in the evaluation planning phase to only focus on new applications and ensure categorisation is accurate
- Link applications with client history so that repetitive non-compliance can be tracked and new applications reviewed using intelligence
- Allow assessors to make approval decisions for module assessments and reduce the time the delegate needs to finalise the report. Assessors to summarise assessments better, for use in the decision document

Modify legislation, regulatory instruments and cost recovery measures

- Simplify legislation to reduce decision making obligations
- Move time frames and fees from the Agricultural and Veterinary Chemicals Code Regulations 1995 to subordinate legislation. Report only annually
- Review and if necessary change fees and levies to reflect the increasing complexity of assessments and the associated additional effort and expertise

INTERNATIONAL COMPARISONS > KEY COMPARITIVE CRITERIA

The following table provides key criteria that should be taken into account when comparing the performance of the Australian agvet registration system to that of other jurisdictions. Due to the very different regulatory systems, fee structures and levels of scientific rigour in place across the various agencies, the use of performance statistics in isolation should be performed with caution.

	Australia APVMA	New Zealand EPA	New Zealand MPI	Canada PMRA	Canada VDD	European Union Plant Protection Products	Japan FAMIC	Brazil
Time frame (min – max)	1-25 calendar months (30-750 days)	10-100 working days	40 working days	80-737 calendar days	2-300 calendar days	2.5 to 3.5 years (912.5-1277 days)	Up to 2 years (up to 730 days)	120 days
Location	Statutory	Statutory	Statutory	Policy	Statutory	Statutory	Statutory	Statutory
Third parties	Regulatory consultants Panel appointed assessors		Registration consultants Accredited Assessors	Grower Requested Own Use (GROU) Committee		Consultants		
Performance target	100%	100%	100%	90%	100%	100%	100%	100%
Recent performance	69% 2016/17	100% 2015/16	55% (approx.) June 2017	Category A 87% Category B 88% Category C 95% 2015/16	Within service delivery standard for 7/9 application types 2015/16	EFSA: 75% (2016) RMS: "delays are commonplace" [1]		Can be up to 6 years[2] Backlog of 6 x those evaluated
Pre-assessment	Administrative		Administrative and technical	Administrative and technical				
Reporting requirements	Quarterly	Annual	As required	Annual	Annual			
Reporting mechanism	Parliament	Annual Report	Industry focussed newsletter	Parliament	Parliament			
Statutory clock	Extension of time for requests for information	Clock stops Can request extensions	Clock stops	Clock stops	Clock stops	Clock stops for requests for information	Rejected if issue not addressed within 1 month	
Review period	Risk based			15 year cycle		Risk based not exceeding 15 years		Risk based triggers

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products
[2] Chemlinked, Brazilian Pesticide Regulation Overview, March 13, 2017

INTERNATIONAL COMPARISONS > FINDINGS

It is difficult to directly compare performance of regulatory bodies due to the different regulatory systems, fee structures and levels of scientific rigour in place. While comparison across jurisdictions is difficult, there is evidence to suggest that the performance issues being experienced by the APVMA are also challenging for other international regulatory bodies.

No other registration system we reviewed reports its performance as frequently as Australia. The published quarterly performance statistics are a commitment made by the APVMA as part of the Australian Government's Regulator Performance Framework (sections 5.1.a and 5.1.b). These performance metrics are developed through consultation with industry and agreed by the Minister. The Canadian Veterinary Drugs Directorate (VDD) reports average time taken to process applications. This may be a more representative way of reporting regulatory system performance, as it reduces the effect low quality and complex applications have on statistics.

An increase in assessment complexity over the last five years has been reported by international counterparts and confirmed by APVMA assessors. For example, at the APVMA, the mean Residue Open Complexity Index (ROCI) almost doubled between 2009 and 2016. This demonstrates that the type of residue assessments now being undertaken by the APVMA, require more time and expertise than they did in 2009. Some regulators charge for actual time taken to process applications, unlike the APVMA's fixed fees which do not allow for increasing complexity and assessment effort.

Technical completeness reviews of data prior to the acceptance of the application (when the regulatory clock starts) is also common internationally, however not currently utilised by the APVMA. Australia is also the only registration system we reviewed in which regulatory clocks do not stop, whilst awaiting information from the applicant.

The use of third parties, with peer review and approval by the regulator, has provided efficiencies for international agencies. Efficiencies have also been gained through the acceptance of assessments performed by other regulators and joint initiatives between free trade agreement partners.

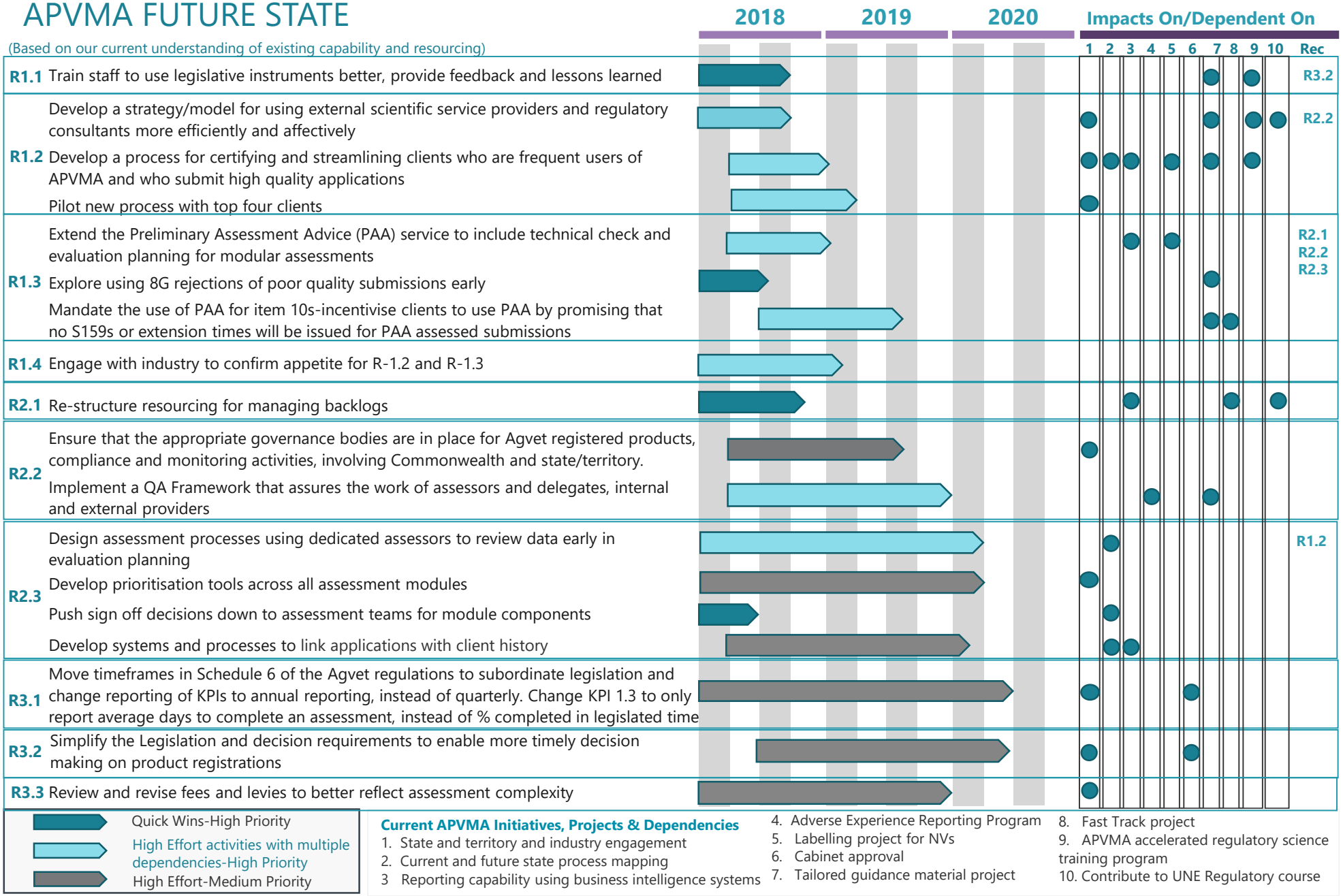
The scheduling of re-evaluations is used by Canada and the EU to ensure that products meet updated criteria.

Engagement of the APVMA with international comparative agencies on the following topics will be critical in achieving improved performance:

- Engage with European Union, Canadian and New Zealand regarding their strong regulatory stances/postures
- Investigate the New Zealand Agricultural Compounds and Veterinary Medicines Registration Review Project
- Monitor the outcomes and actions from the 2016/17 audits in the European Union
- Monitor the European Union Pesticide Legislation Review (2017-19)
- Continue to contribute to OECD agvet chemical initiatives

APVMA FUTURE STATE

(Based on our current understanding of existing capability and resourcing)



Current APVMA Initiatives, Projects & Dependencies

1. State and territory and industry engagement
2. Current and future state process mapping
3. Reporting capability using business intelligence systems
4. Adverse Experience Reporting Program
5. Labelling project for NVs
6. Cabinet approval
7. Tailored guidance material project
8. Fast Track project
9. APVMA accelerated regulatory science training program
10. Contribute to UNE Regulatory course

ACKNOWLEDGEMENT

Reason Group wishes to thank the staff of the Australian Pesticide and Veterinary Medicines Authority for their time, effort and cooperation during the review and in the preparation of this report.

DISCLAIMER

The recommendations within this report should be reviewed and endorsed by the executive before implementation.

The materials presented in this report reflect Reason Group's best judgement in light of the available information at the time of preparation.

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