2017

Operating model for APVMA functions in Armidale

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December 2017

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Pegasus Economics is a boutique economics and public policy consultancy firm that specialises in strategy and policy advice, economic analysis, trade practices, competition policy, regulatory instruments, accounting, financial management and organisation development.

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1. Introduction

This document provides a high-level description of the proposed operating model for the APVMA in Armidale.

All the available evidence suggests that the APVMA will require a delivery model in Armidale that involves fewer regulatory assessment staff than it has traditionally employed.

The model presented in this document was developed from a statement of direction provided in the CEO's 2017 September presentation to staff. The paper draws on more detailed analysis undertaken by Pegasus for the APVMA through 2016 and 2017, including literature surveys, interviews with stakeholders and workshops with staff. Testing and refinement of the final model was undertaken in consultation with managers and targeted groups of staff in November 2017.

The following sections of this document describe a proposed operating model for the APVMA, suggest management arrangements to support the new model and provide comment on a range of implementation issues.

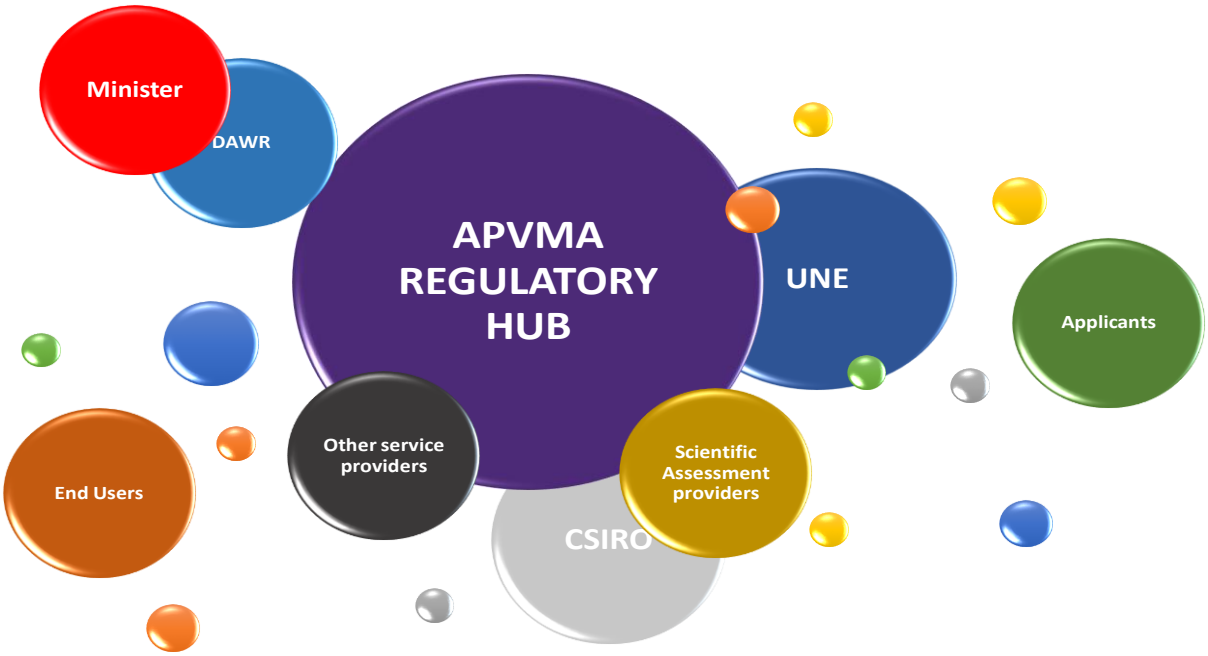
2. A new operating model

2.1 Overview

The APVMA would operate as part of a regulatory hub within a science and agriculture cluster based in Armidale. The APVMA would focus on standard setting, risk management, quality assurance and audit/compliance functions while drawing on a distributed network of scientific assessors and long-term partners for other services.

Figure 1 below illustrates the concept of the APVMA embedded within a larger science-based regulatory system.

Figure 1: Illustration of the concept of the APVMA embedded within its science based regulatory environment



2.2 Description

The APVMA would focus on its core roles of standard setting, risk management, quality assurance, compliance and capacity building. The scientific and management leadership, and most staff, would be located in Armidale. The APVMA expects that up to 150 jobs would be located in Armidale by the completion of the move.

Given the likely availability of experienced assessment staff, a higher proportion of scientific assessments would be provided by external reviewers, subject to technical guidance and standards established by the APVMA. Subject to the availability of suitably qualified staff, the APVMA may also choose to undertake some assessments internally.

A range of other services, including legal, human resources, payroll, communications, finance, IT, facilities management, would be acquired through agency arrangements or through strategic partnerships.

Over time, it is expected that the operating model would be revised as additional information becomes available on the workforce capabilities available to the APVMA and the capacity of industry to partner with the APVMA in the provision of assessment and other services.

Details of the suggested approach as they apply to the APVMA's major current functions are set out in the following Table. For convenience, existing titles for the major functions have been used throughout this paper.

Table 1: Proposed APVMA business and operating models

Business function	**Operating model**
CEO and Office of the CEO	Located in Armidale. Supported by an executive assistant.
Chief Regulatory Scientist	Scientific leadership. Operating through a hub and spoke model with other science providers. Enhanced roles in ensuring science quality, internal capability development and capacity building within the broader regulatory environment. Located in Armidale.
Case Management and Advisory Unit	Focused on administrative and processing support for the Registration function. Located in Armidale. A progressive move to electronic workflows.
Registration Management and Evaluation	Core function. In-house provision of delegated decision-making and risk management, including evaluation planning. Progressive move to digital workflows. Located in Armidale. Some more experienced staff may need to remote work through a transition period.
Scientific Assessment and Chemical Review	A hybrid model consisting of selective in-house provision of more complex and sensitive assessments, an extension of existing panel arrangements and long-term partnering with external providers. Standards setting, assurance

	and capability development functions located in Armidale.
Compliance and Monitoring	Compliance policy and operations management hub located in Armidale. Compliance operations could be developed over time into a State-based network.
Manufacturing Quality and Licensing (MQL)	Existing model for a transitional period. Policy, standards setting and approval function in Armidale. Review functions provided by in-house staff operating from Canberra. The model should be reconsidered when the current policy review of the function is complete.
Legal	Long-term partnering with external providers. Small in-house team to support in-house General Counsel. Located in Armidale.
Corporate	Transactional and processing services would be provided through a shared services arrangement with the Department of Agriculture and Water Resources. A small in-house team would be retained in Armidale to manage staff engagement, HR, budget and finance, procurement and facilities management.

2.3 Structure and reporting lines

The shift to new operating models provides opportunities to simplify the current structure and provide clearer accountabilities for the APVMA's service delivery responsibilities. A suggested structure is illustrated in Figure 2 on the next page.

The proposed new structure seeks to provide:

- A single registration executive so there is a line of sight and clearer accountability across the end-to-end registration process
- Improved coordination between the relationship management (outward facing) and portfolio management (inward facing) functions
- A clear location for specialist assessments and assurance management of third party assessments
- A stronger emphasis on science quality and the development of capability
- A strong Compliance and Monitoring function that is structurally separate from registration and licence approvals
- An enhanced capability for procurement management and the quality assurance of external providers of non-specialist advice and support.

The Registration function includes a broad span of functions that are currently undertaken across two functional units: Registration Management and Evaluation (RME) and Scientific Assessment and Chemical Review (SACR). A single unit would allow for a more integrated approach and more streamlined processing of applications. It will remove many of the costs and complexities associated with managing processes across organisational lines of control.

Figure 2: Possible APVMA top structure

 # Assumes that most assessments and reviews are sourced externally.

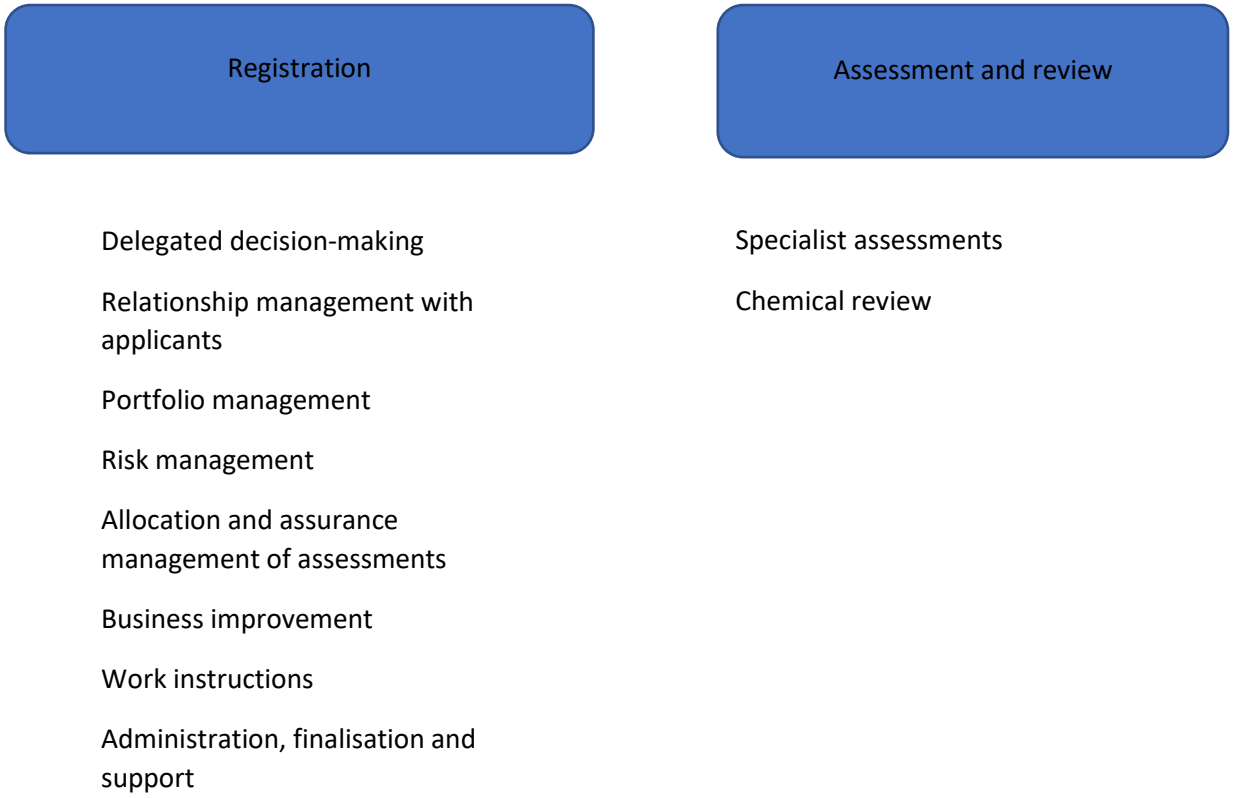
** This function could also be located with other risk management and licensing functions in the Registration unit.*

The suggested structure assumes that the scientific assessment unit would focus on standard setting, the allocation of assessments to suitably qualified external reviewers and the quality assurance of external assessments.

If it is successful in retaining sufficient scientific assessment capability, and in a position to undertake a sizeable proportion of its assessments in-house, the APVMA may wish to consider separating the review element of the scientific assessment and chemical review function from the standards and coordination function located within Registration. The nature of this work is different from the risk management and coordination functions that would be located within Registration and in an outsourcing context there are competitive neutrality reasons for ensuring some structural separation between the commissioning and delivery functions. This would allow the APVMA to commission assessments from its own staff on a basis that can be shown to be transparent, fair and competitively neutral.

If this were the case, the Registration and Scientific Assessment functions could be split as follows.

Figure 3: Alternative structure for the Registration and Scientific Assessment functions



A structure along these lines could potentially create the opportunity to locate the Manufacturing Quality and Licensing (MQL) function in the Registration unit. This would co-locate the APVMA's licensing functions, improve lines of communication between risk managers and MQL staff and facilitate broader career development opportunities for the APVMA's regulatory scientists.

2.4 Management arrangements

The proposed operating model will require changes to the management of some APVMA functions and the underlying business processes and capabilities that support them.

The Executive, Chief Regulatory Scientist and Registration Management and Evaluation functions are largely unchanged from the current model, though it is expected that considerable staff turnover will

be involved, with a consequent requirement for increased training and development, and that the functions will be increasingly digitised over time.

The MQL function would also be unchanged through the transition period, but may need to be revised when the current review of MQL policy and delivery is completed.

The Compliance and Monitoring function would generally operate under similar arrangements to those which currently apply. The bulk of staff in the compliance hub would be in Armidale and it is envisaged that induction and training of new staff would be undertaken in Armidale. The APVMA already supports one State-based compliance officer and could employ additional officers under similar conditions if suitable arrangements can be negotiated with State agriculture departments or with the Department of Agriculture and Water Resources (DAWR).

Significant changes in management arrangements would be required for the Legal, Corporate and Scientific Assessment and Chemical Review functions.

The management of legal services arrangements has been standardised to a large extent across the Commonwealth Government sector. Most Australian Government agencies are currently required to obtain external domestic legal services from legal services providers on the Legal Services Multi-Use List (LSMUL). As of 1 August 2017, there were 149 legal service providers on the LSMUL. While the LSMUL is due to expire on 30 June 2018, the Department of Finance and the Attorney-General's Department are examining an alternative procurement model.

The proposed model for delivery of corporate functions is also well established within the Australian Public Service. The Australian Government is encouraging its agencies to consider the benefits of shared service arrangements for back-office functions. DAWR has indicated that it would be willing to provide all of the APVMA's corporate functions at no additional cost over the current level of service provision. DAWR (2017, p. 97) already provides corporate support functions for 110 locations across Australia including office accommodation, post-entry quarantine facilities, laboratories, data facilities and residences in remote locations.

The development of suitable arrangements to support the external provision of scientific assessment and chemical review functions will be more complex. The APVMA already outsources a significant proportion of its scientific assessments, especially in relation to efficacy and environmental assessments. However, an expansion of the volume of work undertaken by external parties and the extension of these arrangements to include long-term partnering arrangements will require technically proficient in-house regulatory scientists to set standards and allocate work, and the establishment of an appropriate procurement infrastructure within the APVMA.

If the bulk of the APVMA's current assessment activities are provided by external reviewers, the function will require, at a minimum, a manager of external assessment and four teams of two or three regulatory scientists, one each for chemistry, human health and toxicology, environment, residues and efficacy to undertake standards and quality assurance functions. To the extent that additional staff can be recruited or retained, there would be greater scope for the function to include in-house specialist assessment of higher regulatory concern applications.

In addition, the assessment function will require ongoing access to experienced assessment staff to provide training and support for the external providers in the application of regulatory standards and the exercise of appropriate judgements in the assessment of applications. It is proposed that a small unit of experienced staff be established to provide specialised feedback, training and development for the external providers.

An expanded panel and long term contracted partners will also require enhanced governance and management support. It is suggested that management and administrative support for the panel arrangements be provided from within SACR by a small contract support unit. This team would maintain the panel contract arrangements, despatch and receive assessments and maintain timeframe and performance records. Allocation of requests for assessment, quality assurance processes, assessment of the performance of external reviewers and capability development would draw on the technical or scientific expertise of senior regulatory scientists.

3. Implementation

The hybrid model proposed in this report can be implemented within the Government's timeframe for relocation.

None of the recommendations require changes to policy or legislation, though some may require agreements with other agencies.

However, the challenges involved in transitioning to new business and operating models at a time when the APVMA is also seeking to deliver on its ongoing statutory responsibilities, respond to Government demands for further policy reform and relocate its operations to Armidale should not be underestimated.

The construction of the new business models for Armidale should be regarded as a high priority and delivered by a full-time team headed by a senior executive with a direct reporting line to the CEO. In order to insulate the team from the day-to-day and operational pressures of a busy regulator, the team should be separated from the ongoing business and include staff located in Armidale. Arrangements could also be made to facilitate the transfer of staff who wish to relocate to Armidale into this team so they have opportunities to contribute to the construction of the new model and the training of new staff.

The maintenance of a sufficient internal scientific capability will require vigorous efforts to retain and recruit appropriately skilled regulatory scientists.

This will require active management of staff relocations including incentives for staff to relocate and an accelerated recruitment program. The APVMA should also consider targeting staff from overseas pesticide and veterinary chemical regulators, either on permanent appointment or on secondment. Remote working may provide a means of retaining some more experienced staff. However, only some of the functions currently performed are suitable for remote working, and it is highly unlikely that this would be a long-term viable arrangement for the bulk of the staff involved in the function.

Given the challenges in filling all the necessary positions with experienced and fully trained staff, it is suggested that the APVMA prioritise functions for the placement of available staff. Beginning with non-discretionary, core functions, the positions to be filled would be in the following approximate order: delegates and decision makers, risk managers, scientific standards and capability development, quality assurance, scientific assessment and chemical review.

The APVMA will also require access to an expanded range of external providers of scientific assessment services.

A relatively rapid expansion of assessment providers could be achieved in the short term through a tender process to expand the existing panel arrangements.

However, to cover the expected shortfall in disciplines that have not yet been sourced in volume from external suppliers, or where external capacity is limited, the APVMA will also need to quickly

identify a select group of suppliers willing to enter into longer term arrangements and invest in the development of internal capabilities in return for fixed term contracts and a guaranteed minimum volume of work.

Based on the advice of APVMA staff and industry providers, we would expect that the APVMA will want to put its assessment work to the market in tranches based on major discipline areas, such as environment, chemistry, human health, and residues. It would also be sensible for the approach to industry to be developed progressively, based on assessments of market capability, the availability of the appropriate infrastructure (such as standards and guidance material and an in-house team of assurance managers), and the urgency of the need to access external assistance.

An approach to market for long-term, strategic partners could be constructed along the following lines:

> *Determine scope of work and sequencing of the market offer (ie, how much of environmental, human health, chemistry, residues and efficacy?). Sequencing might depend on the depth of the market, the volume of work likely to be sourced, the availability of infrastructure within APVMA to support the offer and the urgency of the need to supplement internal resources.*
>
> *Presentations to potential providers (I)*
>
> *Commence build of internal procurement and QA teams*
>
> *Completion of documentation, including standards, Risk Assessment Manuals and technical instructions*
>
> *A request for information (RFI) informed by contestability pilot inviting expressions of interest for long term strategic partners, statement of capabilities, views on scope, timing, contract period and conditions (such as handling conflicts of interest and access to data)*
>
> *Presentations to potential providers (II)*
>
> *Modification of scope of work, conditions and prices as required based on feedback from market*
>
> *A request for tender (RFT) for services in priority order, determined by capability, urgency, market providers*
>
> *Establish panels over next 12-18 months*

A number of these steps will require considerable advance preparation. For example, while some technical guidance material currently exists, the standards and guidelines will require further development and review before it is in a state that will support new service providers.

Arrangements for handling potential conflicts of interest will be critical to the integrity of the process and its acceptance by industry and the wider public. Suitable arrangements can be developed, but will require considerable work and involve consultation with applicants and potential external scientific assessment bodies. The arrangements set out in the RFT would represent the culmination of a significant body of development work.

Similar sensitivities could be expected in relation to access to data and the protection of intellectual property in a more contestable environment. The APVMA will need to work closely with industry to

develop arrangements that will be acceptable to applicants while ensuring that external scientific reviewers have sufficient information to complete their assessments to a suitable standard.

A progressive build of the model for acquisition of assessment services would provide the APVMA and the industry with experience in the construction of a market of suppliers and build confidence in the concept. It would also provide the APVMA with some protection against the loss of qualified assessment staff.

There are risks in the transition to new business models, but in circumstances where the APVMA is losing a significant proportion of its key staff, we believe those risks can be more effectively managed by moving faster rather than slower. Regardless of the model that is adopted and the transition strategy employed, the APVMA needs to commit to an aggressive program of attraction, recruitment and retention of staff to Armidale so that it can maximise its chances of being fully operational in Armidale by 2019.

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