From: ARTHY, Kareena <Kareena.Arthy@apvma.gov.au>
Sent: Friday, 10 March 2017 3:38 PM
To: Williamson, David; McDonald, Andrew T; Hyett, Richard
Cc: JANIEC, Stefanie; Coordination
Subject: APVMA Inquiry Submission: [SEC=UNCLASSIFIED]
Attachments: APVMA - Letter of Transmission - CEO signed.pdf; APVMA Senate Inquiry submission - Final Version - 10 Mar 17.pdf; Attachment A - APVMA Senate Submission - APVMA Performance Statistics - December Quarter 2016.pdf; Attachment B - Senate Submission - APVMA in Armidale - Relocation Strategy.pdf; Attachment C - Senate Submission - ARAC Terms of Reference.pdf

UNCLASSIFIED

Hi – here is our submission for your records. Cheers Kareena

UNCLASSIFIED

UNCLASSIFIED

From: Coordination
Sent: Friday, 10 March 2017 3:13 PM
To: 'seniorclerk.committees.sen@aph.gov.au' <seniorclerk.committees.sen@aph.gov.au>
Cc: Coordination <coordination@apvma.gov.au>
Subject: APVMA Inquiry Submission: The operation, effectiveness and consequences of the Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016 [SEC=UNCLASSIFIED]

UNCLASSIFIED

Good afternoon

Attached is the Australian Pesticides and Veterinary Medicines Authority's (APVMA) submission to the Finance and Public Administration References Committee Inquiry: The operation, effectiveness and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*.

Attached are the following documents:
1. APVMA letter of transmission
2. APVMA submission and attachments

Please confirm receipt of the submission.

Thank you in advance.

Kind regards

s 47F

s 47F -
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Australian Government
Australian Pesticides and
Veterinary Medicines Authority

10 March 2017

Committee Secretary
Senate Finance and Public Administration Committees
Department of the Senate
PO Box 6100
Parliament House
CANBERRA ACT 2600

APVMA submission to the Finance and Public Administration References Committee Inquiry: The operation, effectiveness and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the opportunity to provide a submission to the abovementioned Inquiry.

This submission provides an overview of the roles and responsibilities of the APVMA and outlines the approach to planning for the relocation of the APVMA to Armidale, how the agency proposes to perform its functions from Armidale and manage risks relating to the move.

I enclose the APVMA submission to the Inquiry.

Yours sincerely

KAREENA ARTHY
Chief Executive Officer

Encl.

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Australian Government

Australian Pesticides and
Veterinary Medicines Authority

MARCH 2017

Submission to the Finance and Public Administration References Committee Inquiry:

The operation, effectiveness and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*

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CONTENTS

FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the opportunity to provide a submission to the Finance and Public Administration References Committee Inquiry: The operation, effectiveness and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016.*

The APVMA is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemical products proposed for supply and use in Australia. The APVMA evaluates the safety and performance of chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected.

On 24 November 2016, Senator the Hon Mathias Cormann, Deputy Leader of the Government in the Senate and Minister for Finance, issued a Government Policy Order which specifies that corporate Commonwealth entities with agricultural policy or regulatory responsibilities are to be located in a regional community that is near a main campus of a regional university recognised for research and teaching in the field of agricultural science. The Government Policy Order applies to the APVMA.

On 25 November 2016, the Deputy Prime Minister and Minister for Agriculture and Water Resources, the Hon Barnaby Joyce MP, announced that the government had approved $25.6 million to fund relocation of the APVMA to Armidale in regional NSW.

The APVMA is undertaking extensive planning to relocate the organisation to Armidale while ensuring it is able to operate out of Canberra throughout the transition period and continue to provide high quality services for the agvet industry, focused on ensuring agvet chemical products are safe, effective and do not impact on trade.

This submission provides a high level overview of the roles and responsibilities of the APVMA and outlines the approach to planning for the relocation, how the agency proposes to perform its functions from Armidale and manage risks relating to the move. An overview of key reform activities being concurrently progressed by the APVMA to streamline the registration process and better align regulatory effort with regulatory risk, including initiatives under the *Agricultural Competitiveness White Paper* is also provided.

1 ROLES AND RESPONSIBILITIES OF THE APVMA

The APVMA has been the statutory authority responsible for the regulation of agvet chemicals since 1993.

Before agvet chemical products can be legally sold, supplied or used in Australia, they must be evaluated and registered by the APVMA through the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The states and territories are responsible for regulating and managing the use of agricultural and veterinary chemical products once they are sold.

More than 11 000 pesticide and veterinary medicine products are currently registered in Australia, including products for treating crop and garden diseases and pests, and medicines for treating agricultural and companion animals. Over time, the scope of products regulated by the APVMA has grown due to advances in technology, increased numbers of generic products, changes to farming practices and a shift to products for the increasingly large companion animal sector.

The APVMA works primarily with companies manufacturing and marketing agricultural chemical products and veterinary medicines, and their representatives, in performing these functions.

The APVMA handles over 5 000 applications each year and takes a systematic, scientific, evidence-based approach to making decisions about whether a chemical or proposed use for the chemical meets statutory criteria. The APVMA evaluates the safety and performance of chemicals intended for sale in Australia, to ensure that the health and safety of people, animals, crops and the environment are protected. Registered products must also not unduly jeopardise Australia's trade with other countries.

The APVMA does not undertake independent research into agvet chemicals. We rely on analysis of data and information submitted by applicants, the majority of which is generated and assessed according to established guidelines.

Our work supports primary industries—agriculture, forestry, horticulture and aquaculture—by allowing the supply of safe, effective animal health and crop protection products. Our work also supports consumers, by ensuring that household and garden pesticides, pool chemicals and pet products are safe to use.

Our role extends beyond registration of pesticides and veterinary medicines to encompass a range of activities aimed at protecting Australians and ensuring that products are safe. We license and audit veterinary manufacturers to ensure adherence to APVMA-prescribed manufacturing standards. We also monitor the market for compliance, and review and take regulatory action on registered pesticides and veterinary medicines when concerns are identified.

The APVMA is a portfolio agency of the Minister for Agriculture and Water Resources.

1.1 Legislative framework

The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act). The Administration Act sets out the role of the APVMA to undertake the responsibilities conferred on it by the states and territories under the NRS.

Functions and powers are conferred on the APVMA by the Administration Act, the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemicals Code* (Agvet Code). The Agvet Code provides for the evaluation, registration and control of agricultural and veterinary chemical products and related matters.

The APVMA is a corporate Commonwealth entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and is nearly fully cost recovered with approximately 40 per cent from application fees and 60 per cent from industry sales levies. The APVMA collects the levies.

1.2 Functions and Powers

The APVMA is responsible for assessing and registering agricultural and veterinary chemical products proposed for supply and use in Australia, and for controlling them up to the point of retail sale.

The key functions of the APVMA, which are set out in section 7 of the Administration Act, are to:

- assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products
- ensure that approvals and registrations for active constituents for chemical products, chemical products and labels for containers for chemical products comply with the Agvet Code, and the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations)
- provide information to the Australian Government and its agencies, and the states and territories, about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and cooperate with the Australian Government and its agencies on matters relating to the management and control of chemical products
- collect and publish relevant information and statistics on approvals and registrations granted and permits and licences issued under the Agvet Code
- with the Australian Government and its agencies, and the states and participating territories, facilitate a consistent approach to the assessment and control of agvet chemicals
- exchange information relating to chemical products and their use with overseas and international bodies that have similar functions to those of the APVMA, and
- report to or advise the Minister on matters relating to the performance of the APVMA's functions.

The APVMA fulfils these functions by:

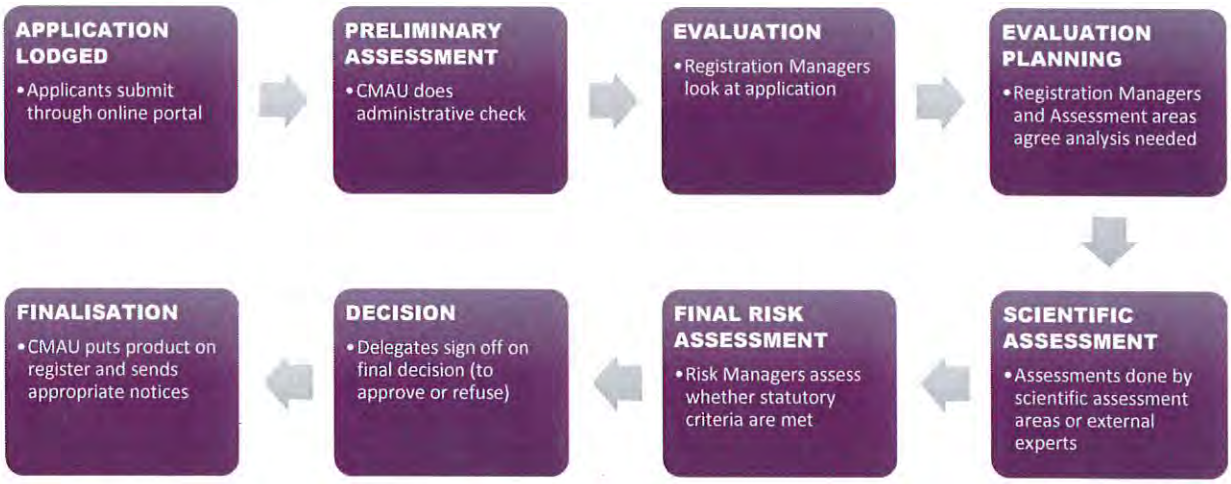
- assessing and registering new chemicals, approving new uses for existing registered products and approving changes to existing registered products
- approving labels for registered products
- assessing and approving active constituents for proposed or existing registered products
- issuing permits for minor use, research, emergency use, import and export of agvet chemicals
- reviewing existing chemicals to ensure they are safe to use
- undertaking compliance and engagement activities to ensure products and active constituents available for use comply with the Agvet Code
- managing a licensing scheme for veterinary manufacturers.

1.3 The work of the APVMA

Assessing applications for registration of agvet chemicals comprises the majority of the work of the APVMA. In doing so, a common process is used across the broad range of applications submitted to the APVMA. In summary (and shown in Figure 1):

- Applicants submit applications online
- Case Management and Administration Unit (CMAU) officers undertake preliminary assessment and the application passes through to regulatory scientists – noting that everything is electronic (not paper based)
- regulatory scientists determine what scientific assessments are needed to make a decision and necessary assessments are commissioned (either internally or through external service providers)
- Once assessments are complete, a decision is made about whether a product can be registered.
- CMAU does the administrative tasks to finalise the registration and ensure entered it is on the register.

FIGURE 1: REGISTRATION PROCESS



The APVMA also runs a licensing scheme for veterinary manufacturers. Third party auditors submit reports to the APVMA for consideration and action. Staff within this team have experience in the manufacturing sector and work is underway to move the systems underpinning the licensing scheme to being fully online.

The compliance and enforcement team operates a risk-based process to assess and respond to reports of non-compliance against agvet legislation. Record keeping systems are in place to ensure any investigations are clearly documented. Compliance staff have been trained in agvet legislation and also hold compliance specific qualifications.

There is a small in-house legal team that provides advice essential to ensuring that APVMA's operations conform to the complex legislative framework under which the APVMA operates.

1.4 APVMA operating model

The APVMA operates from premises in Canberra with one staff member from the compliance team based in Western Australia. APVMA staff are employed under the *Australian Public Service Act 1999*.

The APVMA is structured around four programs:

1. Registration Management and Evaluation – management and decision making on registration of agvet chemical products; primary point of engagement with the chemical industry; and ancillary functions under the Agvet Code and associated legislative framework.

2. Scientific Assessment and Chemical Review – technical assessment and advice for registration of agvet chemical products; assessment of active constituents; and chemical review (reconsiderations).

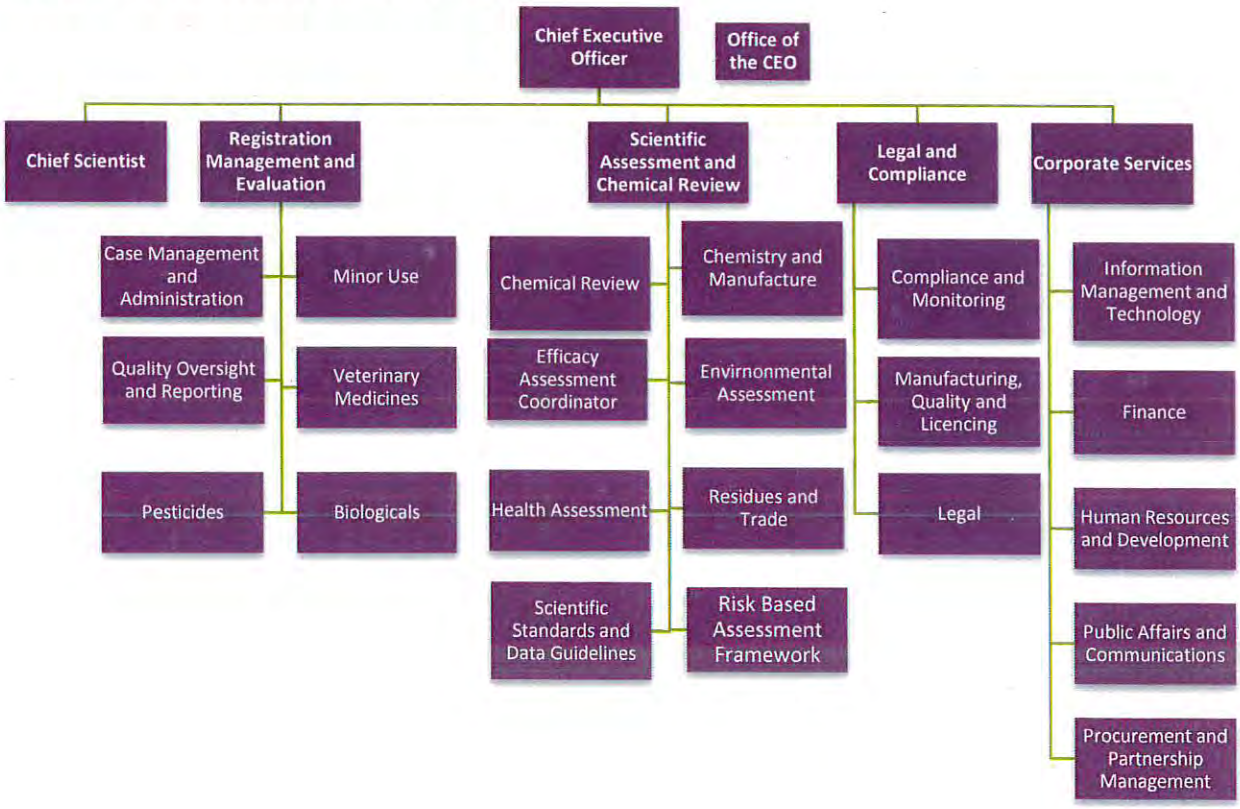
3. Legal and Compliance – legal services; compliance and monitoring of obligations under the Agvet Code and associated legislative framework; and licensing of veterinary chemical product manufacturers.

4. Corporate Services – IT, finance, human resources, communications and contracts and procurement.

These programs are supported by an Office of the Chief Scientist to ensure scientific frameworks and practices meet appropriate standards and take account of emerging technologies, as well as the executive team and coordination support.

The organisation structure is in Figure 2.

FIGURE 2 – APVMA ORGANISATION STRUCTURE



Staff profile

As at 15 February 2017, the APVMA employed 198.1 FTE – 162.1 FTE were employed on an ongoing basis and 36 FTE on a non-ongoing basis. The staffing profile is outlined in Table 1.

TABLE 1: APVMA STAFFING PROFILE – AS AT 15 FEBRUARY 2017

	Casual/Non-ongoing	Ongoing	Total
Regulatory scientists	8.8	74.5	83.3
Case management & administration	4.6	28.5	33.1
Legal and compliance	5	20	25
Corporate – IT	7.6	14.8	22.4
Corporate - Other	7	12.7	19.7
Agriculture White Paper funded positions	2	3.8	5.8
Executive and coordination	1	7.8	8.8
TOTAL	**36**	**162.1**	**198.1**

What is a regulatory scientist?

The work of the APVMA is focused on regulatory science.

Regulatory science involves a pragmatic application of the scientific method for the purpose of making a decision about whether to allow something (e.g. chemicals) to be used within the defined legislative framework and timeframes.

Conventional science involves the application of the scientific method for understanding some physical, chemical or biological phenomena. It tends to be curiosity driven, forward looking and speculative.

What differentiates regulatory science from conventional science is that decisions are based on analysis and interpretation of existing scientific knowledge and, where necessary, assumptions to address data gaps or uncertainty. Regulatory scientists do not generate new lines of enquiry to answer questions, instead relying on available information to make a decision.

While regulatory science incorporates a variety of scientific disciplines, it is in itself a specialised field of science. As well as holding conventional scientific qualifications (for example in toxicology, veterinary medicine and chemistry), regulatory scientists are trained in risk analysis, public administration and regulatory decision making.

Staff movements

From 1 July 2016 to 15 February 2017, 48 staff left the APVMA (this includes four staff who notified their resignation at this date). Of the 48 staff who have left, 20 were regulatory scientists and 35 were experienced permanent staff members (Table 2).

TABLE 2: SEPARATIONS BY PROGRAM AND YEARS OF SERVICE

	Casual/ Non-ongoing	Ongoing	Total	Total years of service
Regulatory scientists*	2	18	20	91
Case management and administration	4	2	6	1*
Legal and compliance	4	5	9	28
Corporate – IT	1	4	5	17
Corporate - Other	2	4	6	29
Executive and coordination	0	2	2	38
TOTAL	**13**	**35**	**48**	**204**

* Staff had less than one year service

Over the same period, 57 staff commenced with the APVMA, the majority being non-ongoing staff, particularly in IT and case management and administration. The figures relating to regulatory scientist commencements are skewed by the recruitment associated with the APVMA taking over the health assessment function from the Department of Health from 1 July 2016.

TABLE 3: STAFF COMMENCEMENTS – 1 JULY 2016 TO 15 FEBRUARY 2017

	Casual/Non-ongoing	Ongoing	Total
Regulatory scientists*	8	9	17
Case management and administration	11	2	13
Legal and compliance	6	1	7
Corporate – IT	10	0	10
Corporate - Other	8	1	9
Executive and coordination	1	0	1
TOTAL	**44**	**13**	**57**

* Four ongoing and one non-ongoing regulatory scientists were recruited to perform health assessment functions following APVMA taking responsibility for from the Department of Health on 1 July 2016.

1.5 Current performance against legislative timeframes

The APVMA releases detailed performance statistics each quarter. The December quarter 2016 statistics were released on 8 February 2017 and are provided at **Attachment A**.

The December quarter 2016 statistics showed that performance against timeframes was steady or improved across all applications (products, permits and actives), except for pesticide product applications. This result was not unexpected due to the loss of key staff from that area and a number of key staff taking leave.

Table 4 provides a summary of the December quarter 2016 key statistics.

TABLE 4: APPLICATIONS PROCESSED – DECEMBER QUARTER 2016

	Commenced	Finalised	Within Timeframe	2015/16 in timeframe	In Progress	In progress still within timeframe
Pesticides	180	156	50%	57%	524	69%
Veterinary medicines	176	164	87%	80%	326	72%
Total Products	356	320	69%	66%	850	70%
Permits	132	110	83%	70%	171	67%
Actives	187	199	88%	70%	300	91%
TOTAL	**675**	**629**	**78%**	**68%**	**1321**	**74%**

There are forward indicators that suggest there will be downward pressure on the timeframe performance statistics in coming quarters:

- The work in progress has increased to over 1300 applications at the end of December 2016 – 150 more applications than at the end of 2015
- Of those applications still being assessed, one in four are overdue, down from one in five applications overdue at the end of the September quarter.

The APVMA is actively managing the backlog to ensure as many applications are finalised as possible within the resources available to the agency and that the time taken to finalise applications after the due date is minimised.

The APVMA is also implementing a range of measures to improve the efficiency of the agency and reduce the regulatory burden on applicants in order to streamline the processing of applications and support performance during the transition. These measures are discussed in Section 5.

2 THE GOVERNMENT POLICY ORDER

On 24 November 2016, Senator the Hon Mathias Cormann, Deputy Leader of the Government in the Senate and Minister for Finance, issued a Government Policy Order (GPO) which specifies that corporate Commonwealth entities with agricultural policy or regulatory responsibilities are to be located in a regional community that is near a main campus of a regional university recognised for research and teaching in the field of agricultural science. A regional community is defined as being a community that is not within 150 kilometres by road of Canberra or the capital city of a State. The GPO applies to the APVMA.

On 25 November 2016, the Deputy Prime Minister and Minister for Agriculture and Water Resources, the Hon Barnaby Joyce MP, announced that the government had approved $25.6 million to fund relocation of the APVMA to Armidale in regional NSW.

The GPO does not explicitly state the APVMA is to move to Armidale. Other locations, like Wagga Wagga, meet the criteria contained in the GPO. However, funding for the relocation provided by Government is tied to the APVMA moving to Armidale. Therefore, the APVMA Chief Executive Officer (CEO), as the statutory officer responsible for the APVMA, made the decision that the APVMA will relocate to Armidale in order to meet the requirements of the GPO.

All decisions about the implementation of the GPO is the responsibility of the APVMA under the provisions contained in the Administration Act.

Background

On 12 May 2015 the Hon Barnaby Joyce MP, Minister for Agriculture, wrote to the APVMA CEO about possible relocation of the APVMA to Armidale or Toowoomba and sought advice about whether the APVMA would be willing to relocate and, if so, which location would best suit the needs of the agency.

The APVMA CEO wrote to the Minister on 31 July 2015 advising that she was unable to support the current proposal to relocate the APVMA to either Toowoomba or Armidale at that time due to the magnitude of expected losses of expertise and experience. The APVMA CEO indicated that, therefore, she would have concerns about her ability to perform her legislative obligations under the Administration Act should the APVMA relocate. However, the APVMA CEO also noted that the *Public Governance, Performance and Accountability Act 2013* may provide an option to make a GPO to effect the relocation and stated she would work with the Minister to enact the government's policies and transition strategies.

The APVMA undertook an extensive program of staff consultation, information sessions, site visits and surveys and sought views from key agricultural and chemical industry groups that engage with the APVMA and the APVMA Advisory Board in preparation of their response on the possible relocation of the APVMA.

As part of the Cabinet process in the lead up to the issuing of the GPO, the Hon Barnaby Joyce MP, Deputy Prime Minister and Minister for Agriculture and Water Resources, wrote to the APVMA CEO on 10 November 2016 seeking advice on the application of the draft GPO to the APVMA, how it will be implemented and how risks will be mitigated. The APVMA CEO responded on 18 November 2016, providing a copy of the Relocation Strategy, which was subsequently made public (at **Attachment B**).

3 THE PLAN FOR RELOCATION

3.1 Context and assumptions

Previous staff surveys (conducted in 2015 and 2016) indicated a limited number of existing staff were willing to relocate to Armidale, with less than 10 regulatory scientists indicating a willingness to move. While the exact numbers of existing staff intending to move to Armidale is unknown at this time, even if there is a significant increase in numbers from these surveys, there will be capability gaps across the organisation, particularly in regard to regulatory scientists. Therefore, it is not feasible to recreate what exists in Canberra in Armidale – new approaches to the APVMA's business must be found.

The Department for Agriculture and Water Resources (DAWR) engaged consultants Ernst & Young (EY) to assess the economic costs and benefits of relocating the APVMA from Canberra to Armidale, to examine the risks of relocation and effective strategies or plans that could address the identified risks and to analyse the economic impacts on Canberra and Armidale. EY identified the following risks:

- the APVMA may be unable to relocate, or recruit and replace, key APVMA executive, management and technical assessment staff
- during the transition and in the short-term, the APVMA may not be able to sustain its rate of effort for registration of new agricultural and veterinary chemical products
- the APVMA may be unable to maintain and grow its capability in the medium-term
- the APVMA may have reduced access to agvet chemical stakeholders.

EY suggested a number of mitigation strategies, including short and medium term phased transition to Armidale, development of a new business model, regulatory scientist training program, relocation/incentive packages, outsourcing technical assessment work and technological solutions to assist collaboration and engagement.

The APVMA considered phasing the transition by moving teams prior to the full relocation. On balance, this approach was not pursued as the current IT system would not support a split operation and the time and resources it would take to set up a secure and fully functional interim office in Armidale would detract from the effort needed to develop the permanent accommodation solution. The logistics and support needed to run the Canberra office and an Armidale office while building a new facility was assessed as being too much of a burden on a small agency and detrimental in the longer run to a smooth transition to Armidale.

The other strategies suggested by EY have been picked up in the planning for the relocation to Armidale.

In terms of long term accommodation in Armidale, an exercise by DAWR in 2016 found that there were no suitable pre-existing buildings in Armidale and that a new facility would need to be built.

The APVMA holds a large amount of confidential commercial and other highly sensitive information. The security and protection of this information is of paramount importance to the companies who register products and to all staff in the agency. Throughout the process of relocation, a major focus will be on ensuring electronic and physical security of information on agvet chemicals.

3.2 Overview of approach to relocation

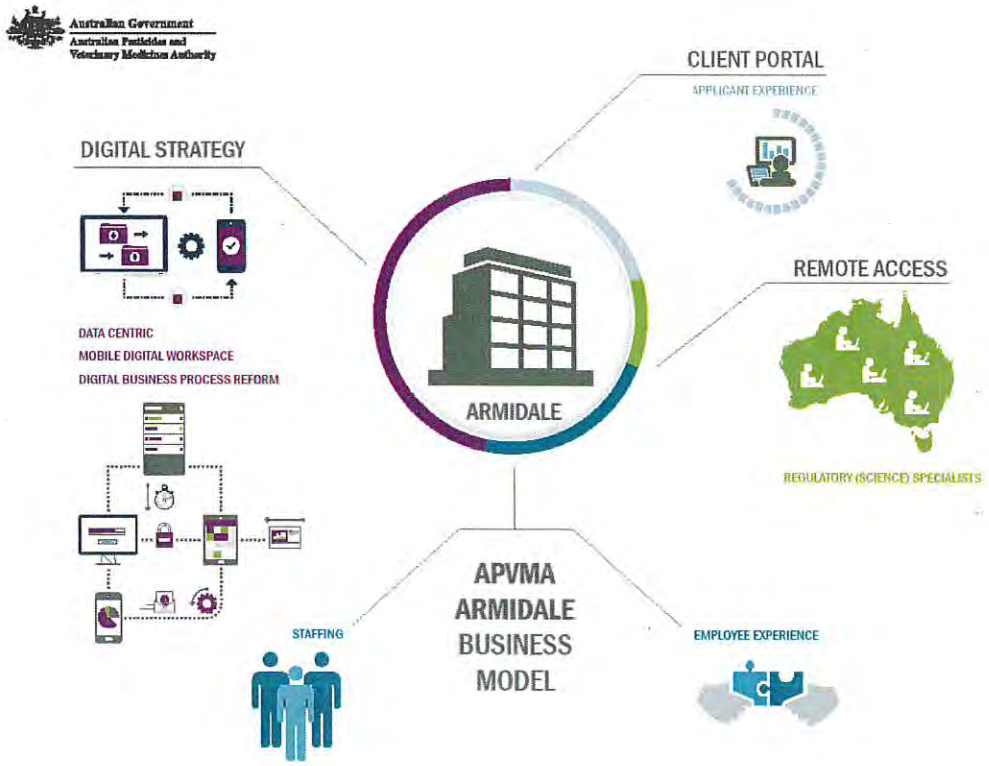
The APVMA released a relocation strategy publically on 2 December 2016 (at **Attachment B**) which outlines the broad activities needed to efficiently transfer APVMA functions from Canberra to Armidale. The relocation strategy is focussed on what needs to happen to move the APVMA, while minimising potential issues during the transition, and to maximise capacity when it operates from Armidale.

The key components to the proposed approach to relocate the agency to Armidale, as represented in Figure 3 are:

- establish a network of regulatory scientists working both remotely and in Armidale
- develop a modern and collaborative workspace in Armidale that can showcase the next generation of public sector operations from regional Australia
- take the client experience to the next level by embracing a full online experience for applicants
- implement a new digital strategy to enable the APVMA to work effectively in this new business model.

The strategy is necessarily high-level as the detailed transition planning is currently underway.

FIGURE 3 – KEY COMPONENTS TO ARMIDALE OPERATING MODEL



This model is currently undergoing careful thought and planning, particularly in terms of making remote working effective on the scale envisaged, and whether feasible alternate approaches exist. However, at this stage, other options to retain access to a critical mass of regulatory expertise have not been identified.

3.3 Relocation activities

There are nine broad categories of work underpinning the relocation of the APVMA to Armidale:

1. Developing the **business model** for how the APVMA will operate in Armidale.
2. Designing and implementing a **digital strategy** to underpin the new business model, including developing a remote working framework and capability.
3. Establishing appropriate arrangements for **property** in Armidale and managing the Canberra facility.
4. Developing **people strategies** for current business needs, the future Armidale workforce, the transition team, retention and relocation, and the health and wellbeing of staff and their families.
5. Developing a **knowledge management** framework to ensure the knowledge and experience of staff leaving the agency can be captured, new starters can be trained more quickly and appropriate information systems designed to underpin the future operation of the APVMA.
6. **Communication and engagement** to ensure APVMA staff are fully informed of progress and available options and for stakeholders to be aware and involved in key elements of the relocation.
7. **Governance and risk management** to ensure the overall projects are managed appropriately and potential risks are identified early and appropriate mitigation strategies put in place.
8. Detailed **planning and logistics** for an efficient relocation.
9. **Finance and reporting** to underpin accountability for the expenditure and effort assigned to the relocation.

All of these activities are linked by a proactive approach to change management.

The progress made in the three months since the GPO was issued is covered in the next section.

3.4 Indicative timeframes

There are five phases planned for the relocation:

- **Phase 1: Planning** (until end June 2017) – focusing on developing the Armidale business model, the digital strategy and the approach for long term accommodation in Armidale. A transition office will be opened in Armidale.
- **Phase 2: Preparation for relocation** (July 2017 to March 2019) – involving the construction of the Armidale facility, digital build and testing, scheduling for the physical removal and finalisation of staff intentions and Armidale workforce strategy.
- **Phase 3: Final systems testing and site preparation** (April 2019 to June 2019) – with final testing of IT systems for use on site and remote set up of Armidale office.
- **Phase 4: Relocation** (from July 2019) – transfer of staff to Armidale and remote working arrangements or assist staff with redeployment or redundancy.
- **Phase 5: Windup of Canberra Office** (from July 2019) – implementation of strategy for accommodation until end of lease period and make good of Canberra building.

These timings are indicative only and will change once more detail is available about the construction of new office accommodation in Armidale.

4 PROGRESS ON RELOCATION ACTIVITIES

The information presented in this section is current as of 10 March 2017.

4.1 Armidale business model

Pegasus Economics has been engaged to assist in developing detail on how the APVMA will operate in Armidale, including a draft organisational structure and governance arrangements. Once finalised the business model will identify key business processes and how they will be performed by the APVMA. The organisational and management structure will allow staff to identify how they fit within the business structure, including detailing those positions which will need to be located in Armidale and those which may be eligible to operate remotely.

The project is exploring:

- Identification of functions and roles that need to be physically provided from the Armidale office
- Other roles and functions that do not need to be provided from Armidale and the potential for these functions to be delivered in other ways
- The capacity of external service providers to fulfil APVMA operational requirements once in Armidale
- The extent that teleworking can support APVMA's functions and roles
- Risks and mitigation strategies attached to new business models
- Governance arrangements, particularly if there is a distributed workforce
- Implications for operational management of the agency
- Changes required, if any, to structures, systems and processes.

Work associated with broader policy and legislative settings are out of scope of this project – ongoing legislative reform and options to reduce regulatory burden is part of the work being led by the Department of Agriculture and Water Resources. Matters relating to the transition period from now to when the APVMA is in Armidale is also out of scope – it is covered under a separate project relating to transition planning.

Consultation has begun with APVMA staff and stakeholders with the final report due end April 2017. This report will then form the basis of the detailed planning and logistics required to move the agency to Armidale.

4.2 Digital strategy

To successfully operate from Armidale, the APVMA will need secure systems that connect staff members with each other and with clients. We will design and build them to be flexible and able to quickly adapt to our changing needs. We will automate processes where possible to increase the efficiency of our business.

The digital strategy focuses on three key elements:

- Becoming a data centric organisation – so information can be managed through a controlled, verified and managed 'single source of truth' with full data integration between systems, processes and applications.
- Enabling a mobile digital workplace – with corporate systems and information able to be securely accessed anywhere and anytime with fully online and intuitive collaborate tools.

- Developing an 'end to end' and interconnected business process operating from one platform, with interconnected business portals and automated touch points and minimal data entry.

The concept provides opportunities to improve efficiency for industry and the APVMA and will reduce the administrative burden on clients and staff in the long run. It will be a significant IT build and, as such, the APVMA is working to ensure that the design of the integrated system and the underlying business processes is well planned.

The APVMA is in the process of engaging a digital partner to prepare a detailed proposal with costings to build and implement a new system for consideration by government this financial year.

The other component of the digital strategy is the design of the remote working framework. Remote working is more than technology – it needs to ensure people working remotely are connected with the workplace and each other, they have appropriate support, training and development, and appropriate mechanisms are in place to manage and monitor workload and performance. There is also a range of work health and safety and security matters that must be worked through.

Preliminary work is underway as part of the business model consultancy in terms of looking at how other agencies manage remote working arrangements. The draft remote working framework is currently scheduled for completion at the end of June 2017.

4.3 Property

There are three components to property relating to the relocation: the permanent building in Armidale, a small transition office in Armidale and the Canberra office.

Armidale – permanent building

The APVMA will require accommodation to be built in Armidale to house the agency. The overall timing of the relocation will be dependent upon the schedule for completing the building.

The intention is to enter a lease arrangement with a private developer. The APVMA received a briefing on 21 December 2016 from the property consultants involved with the expression of interest run by the DAWR to test the Armidale market. A specialist senior executive commenced with the APVMA on 6 March 2017 to manage the procurement process relating to the permanent building.

Armidale – transition office

The APVMA is currently assessing office space in Armidale to open a small transition office to house the CEO, Chief Operating Officer (COO), chief scientist and other members of the executive when they are in Armidale, members of the transition team, community liaison and a small locally recruited administration team to undertake APVMA functions that do not require full security access to online systems or access to physical files. The aim is to have this office operational in March 2017.

Canberra – current office

The lease on the Canberra office ends in October 2020. Management of ongoing maintenance of the building is required and planning for the exit of the premises will be undertaken over the next 12 months.

4.4 People strategies

There are a number of strategies in place and being developed which are critical to support both the continued operation in Canberra during the transition and the relocation of the agency.

Workforce planning - Armidale

A specialist HR company, Bull & Bear, has been engaged to assist the APVMA with workforce issues throughout the transition and to lead the workforce planning for the future business model. The workforce planning component will commence once the business model is finalised, including the design of a graduate program to support the future scientific capacity of the agency. The APVMA has joined the DAWR 2018 graduate program to begin the process of bringing in new graduates from next year. A workforce plan, coupled with a recruitment strategy, will be developed to deliver on the agreed business model for Armidale.

Key assumptions that underpin the anticipated workforce profile for operating from Armidale include:

- **Staff willing to relocate to Armidale** – Previous staff surveys suggest only 10-15 per cent of current staff may consider relocating to Armidale. Nevertheless, every effort will be made to encourage staff to move with the agency to ensure there is a critical mass of experienced people in Armidale.
- **Digital solution** – The APVMA can establish a digital solution that will support a large proportion of regulatory scientists working remotely from anywhere in Australia, working collaboratively and seamlessly connected to the Armidale office.
- **Remote working arrangements** – The APVMA is able to manage the human resource implications including work health and safety, performance management, IT security and physical security of the remote working arrangements.
- **Local recruitment** – The APVMA is able to source suitably skilled people (particularly in the case management, administration and corporate areas) from the Armidale region or attract new staff to Armidale.
- **Use of contractors and outsourced arrangements** – the APVMA is able to secure services from appropriate sources to fill capability gaps.

Workforce strategies – Canberra

The APVMA is experiencing higher than expected staff departures. While the preference is for current staff to remain with the APVMA and transition to Armidale, the APVMA acknowledges that a number of staff will choose to leave prior to the relocation. The APVMA also acknowledges that potential employees may be willing to work for the APVMA while in Canberra, but will not want to move to Armidale. Similarly, there are a number of new recruits who have signalled their willingness to move to Armidale. Therefore, the APVMA has taken a multi-layered approach to attracting potential staff through offering ongoing positions and a range of non-ongoing positions of various terms to suit the needs of the individual.

The APVMA conducted a general recruitment round in late 2016 which attracted over 200 applications. The APVMA is using this pool to select people to fill the multiple vacancies across the agency. Further general recruitment rounds and targeted regulatory science processes are planned and are expected to be a regular occurrence over the next few years.

The APVMA is also exploring options to use specialist employment agencies, different scientific networks and links to other regulators, both in Australia and internationally, to attract staff and fill vacancies. Contractors and consultants are also being used where possible and appropriate.

Health and wellbeing

It is a challenging time for staff and their families as they make decisions about their future. The pressures on staff resulting from staff departures is also significant. The APVMA places a high importance on looking after the health and wellbeing of staff. Change management consultants, Bull & Bear, are regularly on site and monitoring the situation. Twenty-four hour employee assistance arrangements are in place. The APVMA leadership team also proactively addresses issues that may impact on the health and wellbeing of staff and promotes a range of social and health-related activities to support staff.

Retention policy

Given that a relatively small proportion of current staff is expected to move to Armidale, an attractive retention package will be provided to retain as many staff as possible until the Canberra office closes to ensure business continuity, contribution to the design and implementation of the revised business model and digital strategy, training of new recruits and ensuring appropriate knowledge transfer is undertaken. The draft retention policy provided to staff in December 2016 included a retention bonus, professional development, career management assistance and a range of other workplace support. This policy closed for staff consultation at the end of February 2017. Comments are being worked through and finalised with staff.

Relocation policy

The draft relocation policy for people permanently transferring to Armidale has been provided to staff for consultation. Key components of the draft policy include relocation assistance, salary bonuses and return flights to Canberra for one year. This policy closed for staff consultation at the end of February 2017. Comments are being worked through and finalised with staff.

Transition team

The relocation will be led by the COO, who is overseeing all corporate and relocation related services to ensure the relocation happens with as minimal disruption as possible to services to support business as usual. Following approval by the Public Service Commissioner in December 2016, two new senior positions have been recruited to support the COO:

- **Relocation Operations Manager** – responsible for the overall planning, scheduling and delivery of the logistics of the relocation (including property related matters), as well as ensuring appropriate risk management, procurement, governance, record keeping and staff liaison arrangements are in place.
- **Digital Strategy Executive Director** – responsible for ensuring the digital strategy is designed and delivered to underpin the Armidale business model, including overseeing linkages to 'business as usual' systems and the new digital strategy as well as the transition from the existing system to the new system.

The Relocation Operations Manager commenced on 6 March 2017 and the Digital Strategy Executive Director commenced on 23 February 2017. These leaders are in the process of forming their teams. A range of contractors and consultants will be engaged for specialist tasks.

4.5 Knowledge management

Knowledge management is a high priority, given the numbers of people leaving the agency and the need to bring on new (inexperienced) staff quickly. Bull & Bear has begun work on capturing the key elements of information and knowledge needed for the various job families within the APVMA and is in the process of designing a framework to ensure knowledge is captured and conveyed during the transition and appropriate strategies are in place to manage information under the new Armidale business model.

4.6 Communication and engagement

A communication strategy is being implemented to support staff and stakeholders during the transition as well as manage associated media and issues. Seftons Communications has been engaged to manage the communications surrounding the relocation.

The focus to date has been on providing information to staff and handling media following the November 2016 announcement. A program for communicating to stakeholders began in January 2017, as well as a program to provide information about the Armidale region to staff. Senior APVMA staff members visited Armidale on 14 December 2016 to meet with a range of local stakeholders, including the Armidale Regional Council and the University of New England. Regular visits to Armidale are planned to ensure the integration of the APVMA into the local community is a positive experience for all parties.

APVMA staff are actively involved in the design of the Armidale business model and in other elements of the relocation. Stakeholders will be engaged in various activities relating to the relocation, primarily through the APVMA Relocation Advisory Committee (ARAC).

The APVMA Relocation Advisory Committee

ARAC was established by the APVMA CEO to provide strategic advice on major aspects of the relocation and the transition of the APVMA from Canberra to Armidale. ARAC is made up of representatives from the APVMA, peak industry bodies as well as Armidale Regional Council, University of New England and the Department of Agriculture and Water Resources.

ARAC is not a decision making body and does not have any direct say on the day-to-day management of the relocation project or the allocation of resources. The purpose of ARAC is to:

- assist with the design of the business model for the APVMA operating out of Armidale
- provide input to the design and delivery of the digital strategy to underpin the Armidale business model
- identify strategic risks and advice on mitigation strategies related to the relocation of the APVMA
- identify relocation related stakeholder issues and advice on engagement and communication activities and issues management (as appropriate)
- provide high level oversight of the progress against key milestones
- consider other relevant issues referred to ARAC by the APVMA CEO.

The ARAC Terms of Reference are at **Attachment C**.

4.7 Governance and risk management

The development and transition to a new business model for the APVMA operating out of Armidale is a complex task. Identifying risks and mitigation strategies is a critical part of the planning phase. The APVMA Executive and ARAC will be the primary forums for continual analysis and updating of the risk framework, with a specialist risk management position to be established as part of the transition team. The APVMA Audit and Risk Committee will also play a critical function in ensuring appropriate frameworks are in place to identify and manage risk.

The key strategic risks impacting on the APVMA that relate to current operations from Canberra and the transition to Armidale have been identified as risks to:

- delivery of legislative obligations and completion of the relocation in a timely manner
- potential for making inappropriate decisions that result in significant harm, loss or liability
- maintenance of organisational capability and staff wellbeing
- relationships with stakeholders
- digital and systems capability
- financial sustainability.

There is a high risk of impacts on business continuity throughout the transition period from anticipated staff departures (particularly the possibility of losing highly skilled and experienced staff), the lengthy time it takes to train new starters, and the re-tasking of existing staff to support critical work underpinning the transition. The impact on the quality and timeliness of decision making will be carefully monitored and managed. The APVMA has also begun work on a fast track basic training program for regulatory scientists commencing with the agency.

The ability of the APVMA to meet legislated timeframes will be affected during the transition to Armidale. The APVMA continues to look at ways to improve the efficiency of business systems and other measures to reduce the burden on staff in performing their duties. The APVMA also recognises the potential uncertainty for applicants in knowing when their applications will be finalised. Work is underway on mechanisms to more easily provide applicants with expected completion dates, including ways to communicate any uncertainty around timeframes.

4.8 Planning and logistics

Detailed planning for the logistics of the move will commence shortly, given the recent engagement of a Relocation Operations Manager. The overall timeframes will be driven by timeframes associated with the building of office accommodation in Armidale.

4.9 Finance and reporting

A budget of $25.6 million has been provided by government to support the relocation. Additional funding for the digital strategy will be determined by government in coming months. The detailed budget is currently being developed now that the Relocation Operations Manager and the Digital Strategy Executive Director has commenced.

5 APVMA REFORM INITIATIVES

As well as managing the relocation of the APVMA to Armidale and the processing of applications, the APVMA is continuing its long term change agenda for efficiency improvements, implementing lower regulatory pathways to registration and improving customer service.

5.1 Business continuity and improvements

Business continuity continues to be a focus with people leaving and new recruits starting. In addition to the recruitment underway, the APVMA is adopting a range of measures to ensure legislative obligations can be met with a less experienced workforce, focussing on improving efficiency and reducing regulatory burden and assessment effort.

Industry have requested that the APVMA continues to prioritise applications according to existing methods. The priority at present is on how more accurate estimates of application due dates can be provided to applicants and mechanisms by which applicants can shift priorities for assessments within their own portfolio of applications.

The APVMA continues to look at its processes to identify efficiencies, with a significant process improvement recently implemented which will significantly reduce the time and effort in assessing environmental impacts of veterinary medicines. Work is also underway with streamlining the issuing of notices for refusal or approval of generic products, which will significantly reduce the effort required in finalising these applications.

The APVMA is undertaking a project focusing on end to end registration to improve internal efficiency and transparency in dealing with registration processes. The objective of the project is to design and implement a systematic way to use workflow for handling applications from beginning to end, supported by effective systems and processes. Current state processes have been developed for several application types and work is underway to identify systems and process improvements. While the main focus of this work is to inform the development of the new digital strategy, the outcomes will also benefit current operations.

The APVMA is also focusing on ways to make it easier for applicants to make an application, while at the same time ensuring new starters are able to more quickly understand the legislative requirements for assessment of the variety of applications dealt with by the APVMA. To that end, the APVMA has developed the concept of the 'Top 20', which is a profile of the most common applications submitted to the APVMA. For each item in the Top 20, there will be targeted guidance material for applicants (as opposed to them having to gather information from a variety of sources) and assessment guidelines for staff, which will cut down the initial phases of evaluation and avoid delays through asking for unnecessary information. The APVMA is discussing this concept with industry in March 2017 to finalise the 'Top 20' and map out a process for its implementation.

5.2 Taking a lower regulatory approach to registration

The 2016-17 budget included $7.3 million over four years to implement the APVMA's components of the Agricultural Competitiveness White Paper reforms. The scope of this work will primarily focus on investigating and implementing lower regulatory approaches for all applications that the APVMA receives for active constituent approvals, product registrations and variations.

The APVMA has developed a plan for gradually introducing these alternate and more efficient pathways over the next two years, supported by funding allocated through the White Paper. The activities outlined below fall within the scope of this program.

International assessments

The APVMA has developed guidance for industry on accepted international data, standards and assessments including OECD guidelines, assessments and standards by OECD members and agencies. A technical policy framework will be published in March 2017 following extensive consultation with industry.

The key features of this framework are:

- Definitions of acceptable international assessments, including their potential scope and a list of organisations whose assessment reports the APVMA will accept,
- A clear statement that the active constituent or product which is the subject of the international assessment must be identical to the active constituent or product intended for approval or registration, respectively, in Australia,
- Listed criteria that the international assessment must fulfil to be acceptable to APVMA,
- Requirements covering the submission of multiple assessments and underlying data or studies
- Confirmation of how the APVMA will use the data provided, including a clear statement that the APVMA does not simply adopt the conclusions of an international assessment—each international assessment must be fit-for-purpose and supported by studies that fulfil our regulatory (data) requirements, and
- Guidelines for the submission of an international assessment.

The APVMA has provided guidance to staff on how to handle international assessments and it is now up to industry to submit international assessments in support of registration applications. Industry are being encouraged to discuss any international assessments with the APVMA prior to submission to ensure the best use can be made of this data and information.

Technical guidance

The APVMA has published adopted relevant international technical guidance material, including from the OECD. Re-working of applicable APVMA data guidelines to better align with international technical guidance material (including the incorporation of OECD Data Point Numbering into the pesticide data guidelines) and providing greater clarity to applicants on the Australian-only information contained in APVMA data guidance material is required.

Contestable assessment services

The APVMA is conducting a pilot for efficacy assessments to be obtained by applicants prior to submitting an application. The pilot commenced on 1 July 2016 utilising approved external scientific reviewers already engaged by the APVMA and will conclude in June 2017. Companies can nominate to participate in the pilot. To date, two applications have been received by the APVMA through this pilot.

Crop groupings

The APVMA is working with Department of Agriculture and Water Resources on a project to improve access to chemical products for use on minor crops by streamlining registration requirements.

An official Australian crop groups list, and the individual crops which form these groups, has been finalised and published. The next phase to be progressed is to review and update data guidelines to identify representative crops from each group which can be used to generate acceptable data for safety, efficacy and trade criteria.

The APVMA is also about to commence a project to determine which permits are suitable for conversion to full registration.

Enhancing user experiences

The objectives of the enhanced applicant experience suite of projects are to obtain a clear understanding of what applicants want from the APVMA, to explain more clearly how to make a registration application and navigate the application system, and improve technical guidance material.

A Usability Review of our online services/channels is complete. Opportunities for short/medium and long term have been identified and work is underway to implement these.

Fully modular assessment system

The APVMA is defining the conceptual framework, business requirements and legislative changes required to support a fully modular assessment system for applications. This will enable tailoring of assessments and regulatory treatment to individual applications. The modular system will be flexible and better able to make use of international or third party assessments and crop groupings. A proposal is being agreed with the Department of Agriculture and Water Resources for inclusion in broader reform to agvet chemical regulation. Consideration of the design requirements will be included in the digital strategy for operation of the APVMA from Armidale.

Fast-track registration

Since 29 July 2016, the APVMA has piloted a fast-track registration pathway for companies wanting to repack their own products. As at 21 February 2017, we have received 17 applications: four are being processed; eight did not meet the fast-track criteria and have been processed via the normal Item 8 pathway; and five eligible applications had their products registered in an average of 10 days. This compares to the legislative timeframe for these types of applications of three months and is also less than the 21-day timeframe we set ourselves for the pilot.

The pilot used IT enhancements and internal process revisions to reduce the time taken to process these applications. This initiative was directly responsible for identifying the business change to allow upfront payment of the full application fee, implemented on 24 November 2016.

The APVMA is continuing the fast-track registration pathway for applications that meet the same criteria set for the pilot. Before we widen the scope for the types of applications that can use the fast-track pathway, we need to make further enhancements that will make processing these applications less onerous. We are reviewing the lessons learnt from the pilot to identify business processes and legislative changes that could improve the current process.

Standards for low risk products

Registration standards will define the conditions under which the APVMA is satisfied in relation to a particular group of products. Products that meet the requirements of the standard could achieve registration through the fast-track registration system. The APVMA will need to develop guidance material for industry in developing such standards. Monographs for low risk ingredients or classes of ingredients would again define the conditions under which such an ingredient would be considered 'low risk'. Consultation with dairy sanitiser and anti-fouling paint industry members is ongoing to determine how this approach may be useful for those products. The APVMA will then explore this option with other industry sectors where appropriate.

Notifiable variations

In September 2016, the APVMA expanded the list of notifiable variations – minor changes that are accepted by notification, rather than an application – as an outcome of the lower regulatory approaches to registration project. Five new items were added to the list of notifiable variations which allow companies to make minor changes to active constituents, products and labels through a simpler and faster process of notification. The APVMA will continue to look for other application types that may be suitable to be a notifiable variation.

GLOSSARY

Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
Agvet chemical products	Agricultural and veterinary chemical products
Agvet Code	*Agricultural and Veterinary Chemicals Code*
Agvet Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
Agvet Code Regulations	*Agricultural and Veterinary Chemicals Code Regulations 1995*
ARAC	APVMA Relocation Advisory Committee
APVMA	Australian Pesticides and Veterinary Medicines Authority
CEO	Chief Executive Officer
COO	Chief Operating Officer
DAWR	Department for Agriculture and Water Resources
EY	Ernst & Young
GPO	Government Policy Order
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
OECD	Organisation for Economic Co-operation and Development
PGPA Act	*Public Governance, Performance and Accountability Act 2013*

ATTACHMENTS

Attachment A	APVMA Performance Statistics - December Quarter 2016
Attachment B	APVMA in Armidale: Relocation Strategy
Attachment C	The ARAC Terms of Reference

Australian Government

Australian Pesticides and
Veterinary Medicines Authority

JANUARY 2017

APVMA Performance Statistics

December Quarter 2016

TABLE OF CONTENTS

1 OVERVIEW

The APVMA commenced assessment of 1128 applications in the December quarter 2016, including 655 new applications for product registration, active approval, permits and preliminary assessment.

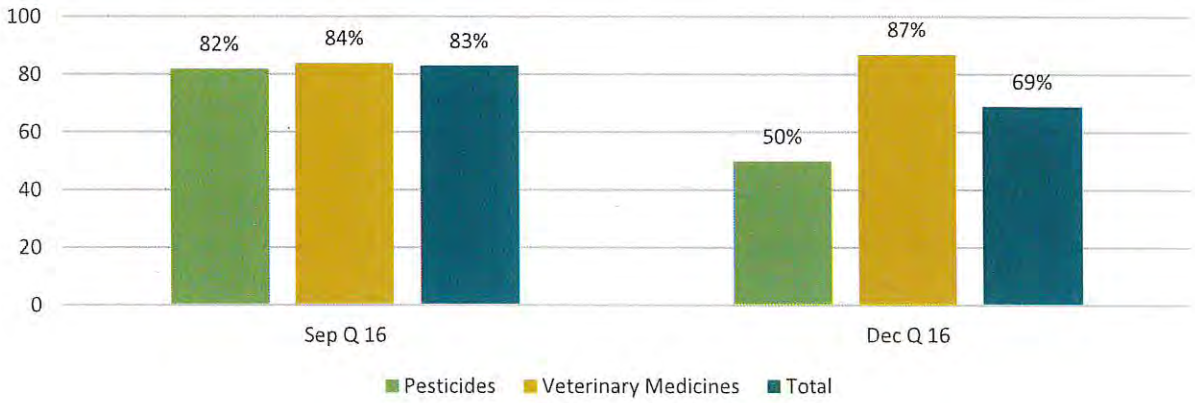
Timeframe performance for product registration, active approval and permits improved slightly in December quarter 2016, and was well above performance a year ago.

77% (Sep Q 16) → **78%** (Dec Q 16)

65% (Dec Q 15)

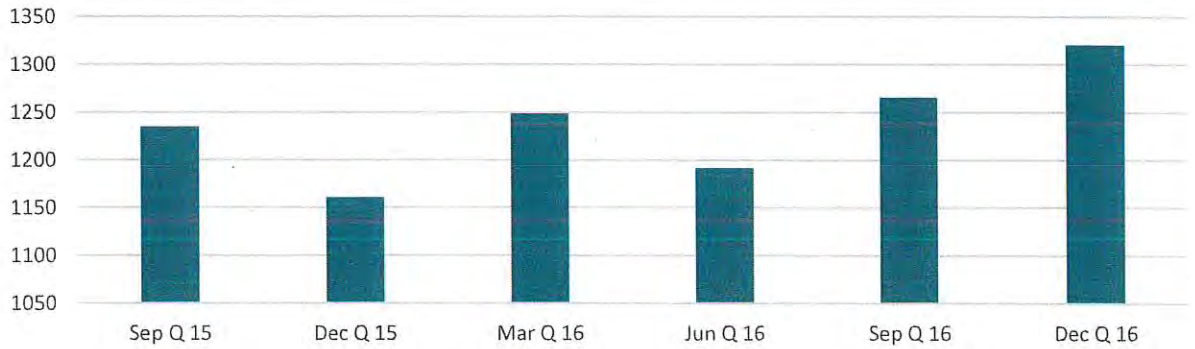
Timeframe performance for product registrations fell to 69 per cent due to a drop in pesticide registrations completed within timeframe. Timeframe performance for veterinary medicine registrations improved.

TIMEFRAME PERFORMANCE - PRODUCTS



Work in progress rose slightly, with 1321 applications in progress as at 31 December 2016 – an increase of 55 applications from 30 September 2016. Increases in work in progress for product and permit applications were slightly offset by a drop in applications for active approvals.

WORK IN PROGRESS



Work in progress still within timeframe dropped to 74% in the December quarter (from 79% in the September quarter) – that is one in four applications being considered by the APVMA were overdue at the end of 2016. As the APVMA clears the overdue applications, it will (negatively) impact on timeframe performance in future quarters.

2 ANALYSIS BY TYPE OF APPLICATION

2.1 Summary

SUMMARY OF ACTIVITIES RELATED TO REGULATORY DECISIONS – DECEMBER QUARTER 2016

Types of regulatory decisions*	Commenced	Finalised/issued	In progress
Pre-application assistance	32	32	37
Product registration—pesticides	180	156	524
Product registration—veterinary medicines	176	164	326
Actives	187	199	300
Permits	132	110	171
Items 8L, 8M, 8P	22	96	10
Technical assessment (Item 25)	7	1	16
Notifiable variations	186	141	84
Import consents	112	115	0
Certificates of export	94	95	10
Total	1128	1129	1478

*See description of application types.

2.2 Pre-application assistance

In December quarter 2016:

- 32 applications were received
- 32 applications were finalised
- 37 applications were in progress at the end of the quarter.

PRE-APPLICATION ASSISTANCE – DECEMBER QUARTER 2016

	Received	Finalised	Within timeframe	In progress
Tier 1 (1 month)	12	9	2	10
Tier 2 (2 months)	17	19	3	23
Tier 3 (3 months)	3	4	1	4
Pre November 2015*	0	0	0	0
Total	32	32	6	37

* This includes all PAAs received under the previous process.

Pre-application assistance (PAA) is an optional, three tiered, fee-based service provided to applicants to provide them with advice before they submit an application for registration. The timeframe for each tiers is based on the complexity and effort required to provide the assistance.

2.3 Preliminary assessment

In December quarter 2016:

- 99 per cent were completed within the 30 day timeframe
- 564 were received
- 654 were processed
- 97 per cent went into evaluation.

PRELIMINARY ASSESSMENT – DECEMBER QUARTER 2016

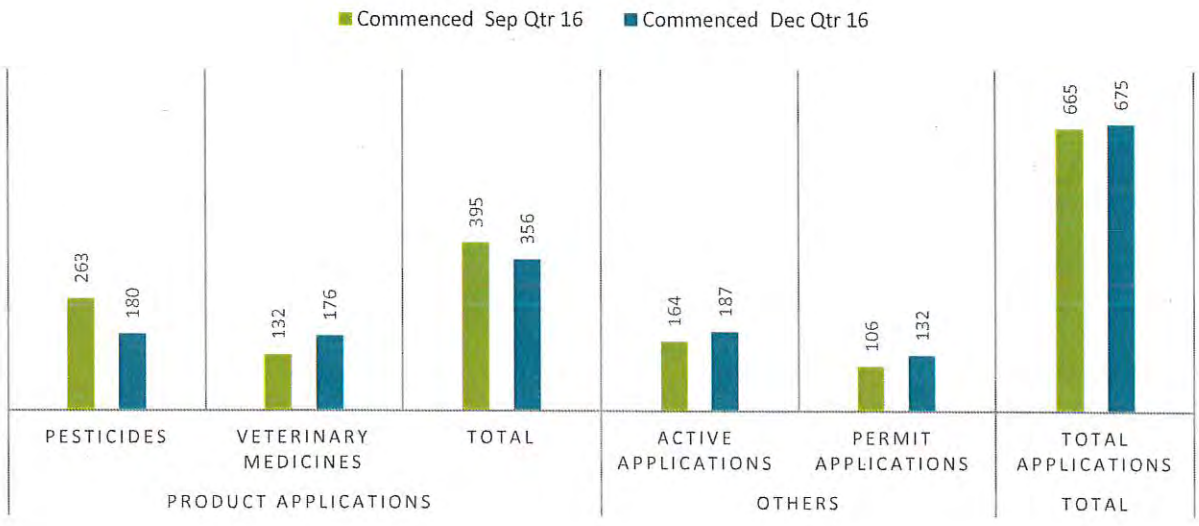
Application Type	Received	Completed	Refused	Withdrawn	Within timeframe
Pesticides	224	190	0	0	100%
Veterinary medicines	93	87	0	0	100%
Total Products	**317**	**277**	**0(0%)**	**0(0%)**	**100%**
Permits	124	130	5	3	98%
Actives	214	190	0	0	100%
Total	**655**	**597**	**5(0.8%)**	**3(0.5%)**	**99%**

Preliminary assessment is an administrative check of all applications received to ensure the information necessary to proceed to a full evaluation is present. The timeframe for preliminary assessment 30 days from receipt.

2.4 Applications commenced

In December quarter 2016:

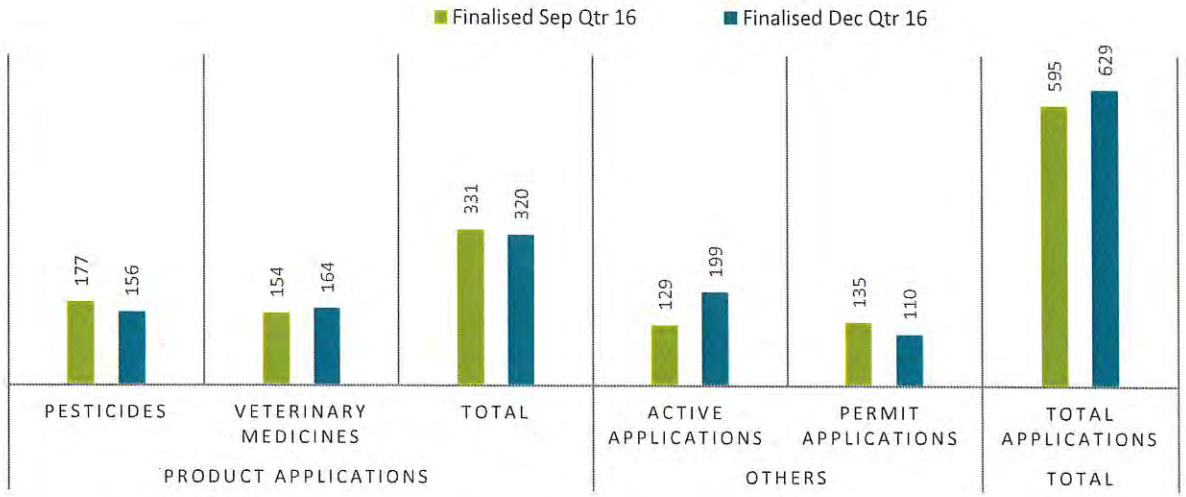
- 675 applications were commenced
  - 356 for products
  - 187 for actives
  - 132 for permits



2.5 Applications finalised

In December quarter 2016:

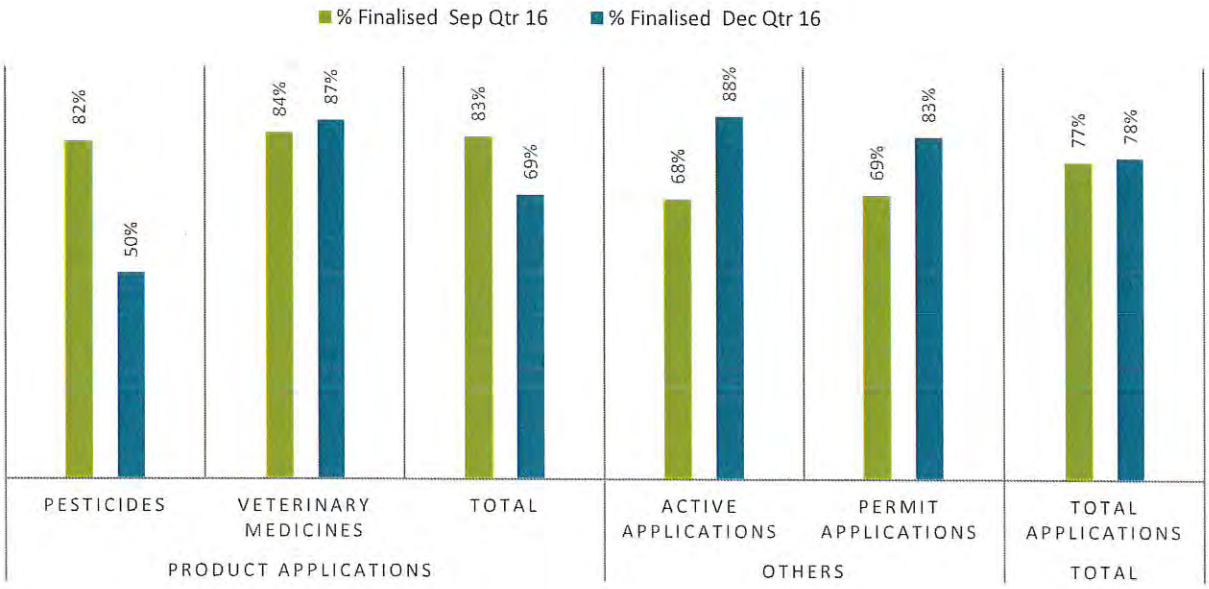
- 629 applications were finalised
  - 320 for products
  - 199 for actives
  - 110 for permits



2.6 Timeframe performance

In December quarter 2016, timeframe performance results product applications were:

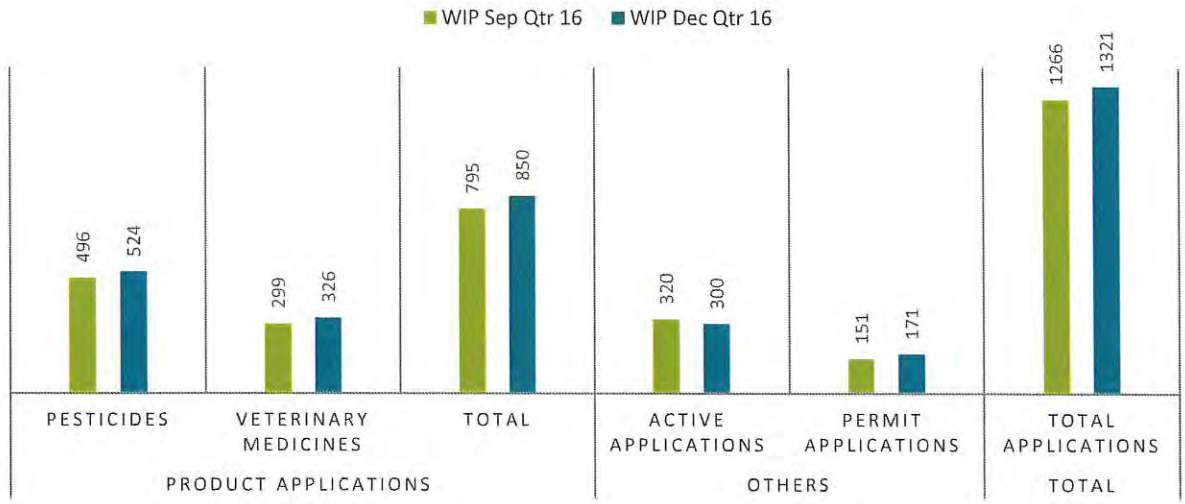
- 50 per cent for pesticide products
- 87 per cent for veterinary medicines products
- 88 per cent for actives
- 83 per cent for permits

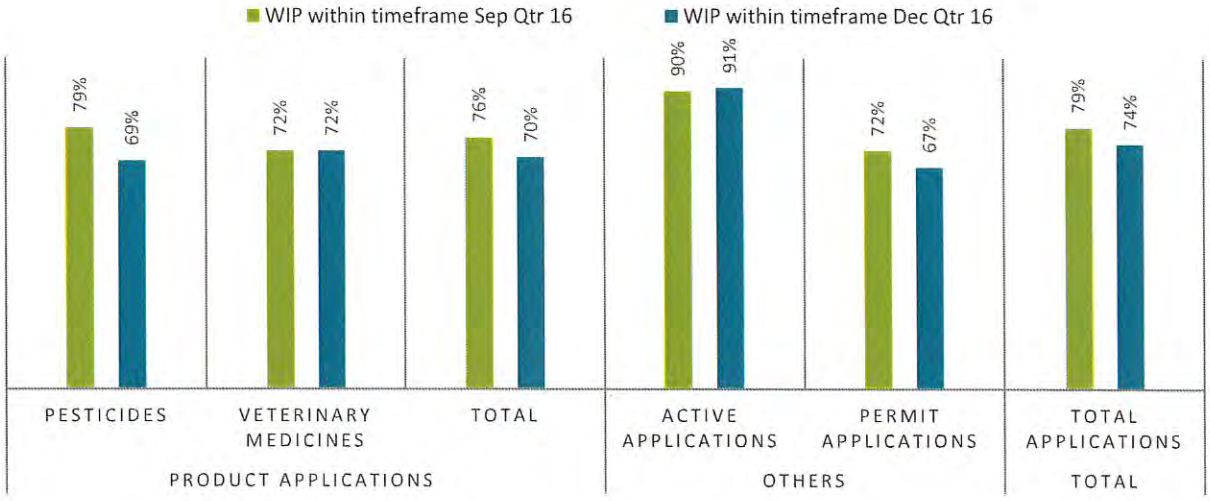


2.7 Work in progress

At the end of December quarter 2016, there were:

- 1321 applications in progress
  - 850 product applications
  - 300 active applications
  - 171 permit applications
- 74 per cent were within timeframe





Work in progress is an indicator of the future workload of the APVMA. It is calculated as the number of applications still in evaluation at the end of the quarter.

2.8 Technical assessment, notifiable variations, holders and nominated agents

In December quarter 2016:

- Four technical assessments on data packages were finalised
- 150 applications to change (or create) a holder or nominated agent (item 8L, 8M, 8P) were finalised
- 263 minor changes to the details of a registered product, active or label (notifiable variations) were finalised.

OTHER REGULATORY ASSESSMENTS – DECEMBER QUARTER 2016

Assessment type	Commenced	Finalised	In progress	Finalised within timeframe (%)
Technical assessment	7	1	16	0%
Items 8L, 8M, 8P	22	96	10	8%
Notifiable variations	186	141	84	100%

2.9 Consents to import

In December quarter 2016, 107 consents to import were issued.

IMPORT CONSENTS – DECEMBER QUARTER 2016

Quarter	Received	Finalised	Issued	In progress	Finalised within timeframe (%)
1	148	141	132	17	92%
2	112	115	107	0	96%
Total	260	256	239 (93%)	0	93%

Consents to import are issued to allow importation—in limited circumstances—of unregistered products or unapproved actives into Australia, when a legitimate reason exists for a person or company to have possession of the chemicals in Australia. There is no statutory timeframe for consents to import—the APVMA seeks to process these within 14 days.

2.10 Certificates of export

In December quarter 2016, 167 certificates of export were issued.

EXPORT CERTIFICATES – DECEMBER QUARTER 2016

Quarter	Received	Issued	Not Issued	In progress	Finalised within timeframe (%)
1	60	64	0	3	69%
2	94	95	0	10	87%
Total	154	159	0	10	80%

Before accepting exports of a chemical product from Australia many countries require an assurance from the government authority responsible for regulating the product in Australia. This is provided by the APVMA in the form of a certificate of export. There are no statutory timeframes for the APVMA to process these but try to complete them within 20 working days.

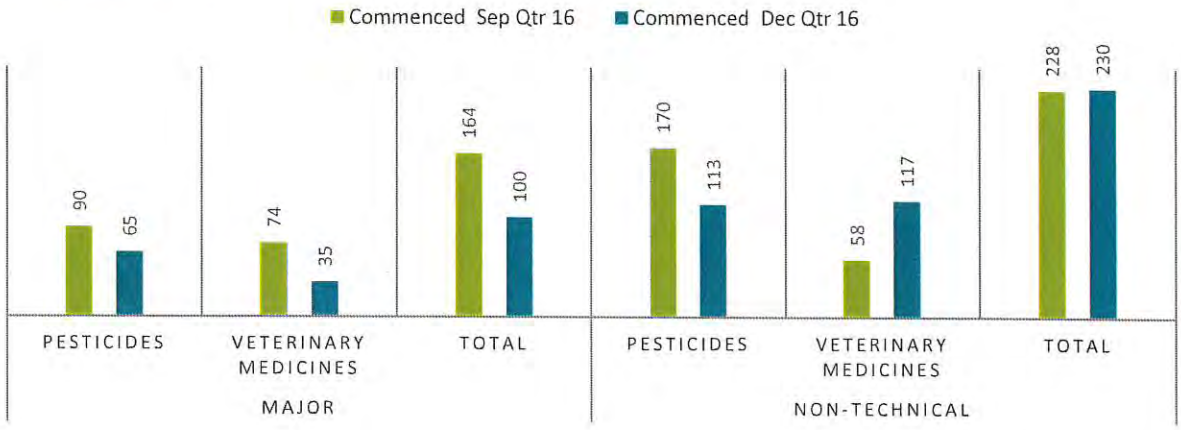
3 APPLICATIONS IN DETAIL

3.1 Major and non-technical product applications

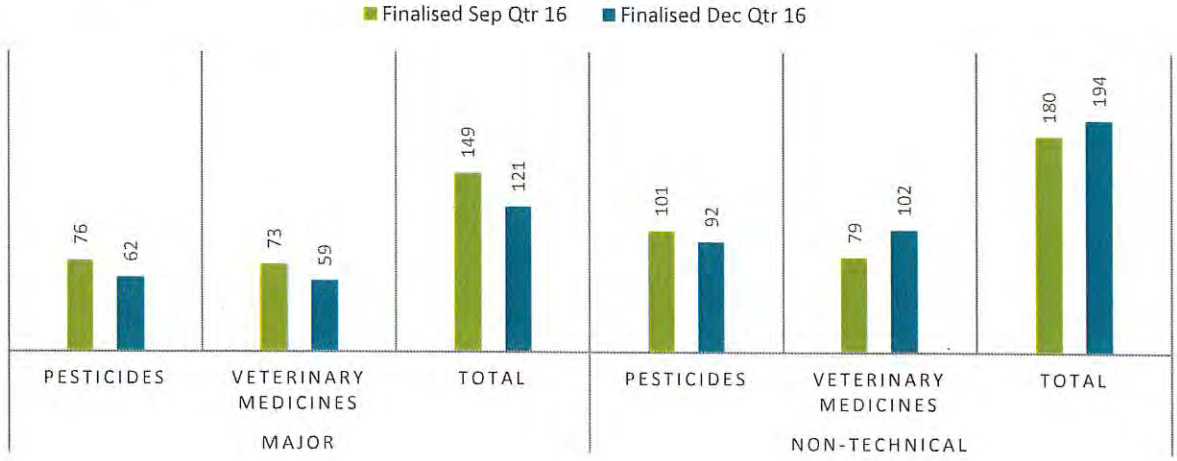
In December quarter 2016:

- 47 per cent of applications requiring major assessment for pesticides were completed within timeframe
- 69 per cent of applications requiring major assessment for veterinary medicines were completed within timeframe
- 51 per cent of non-technical applications for pesticides were completed within timeframe
- 97 per cent of non-technical applications for veterinary medicines were completed within timeframe

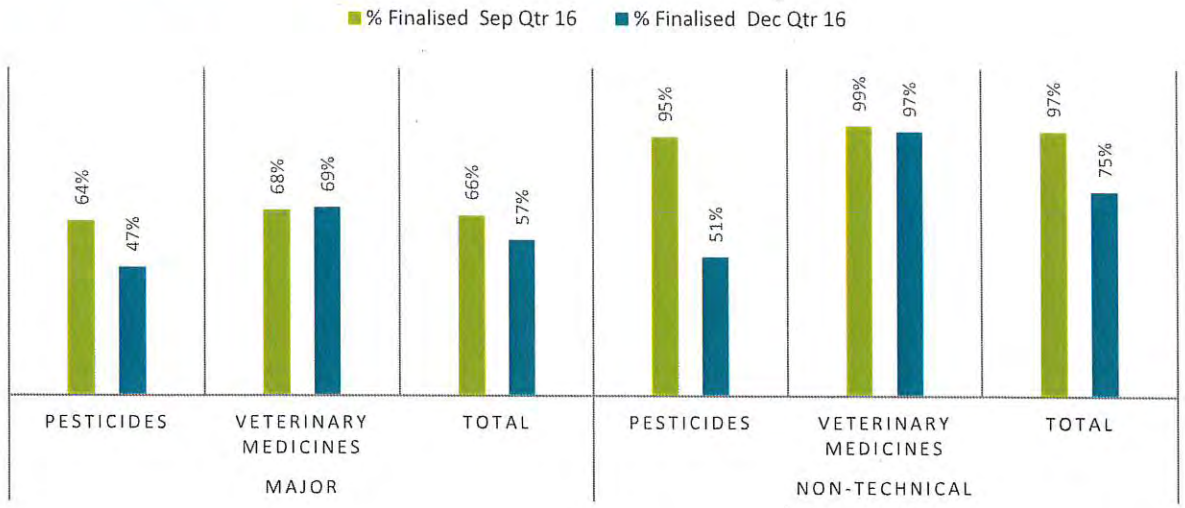
COMMENCEMENTS



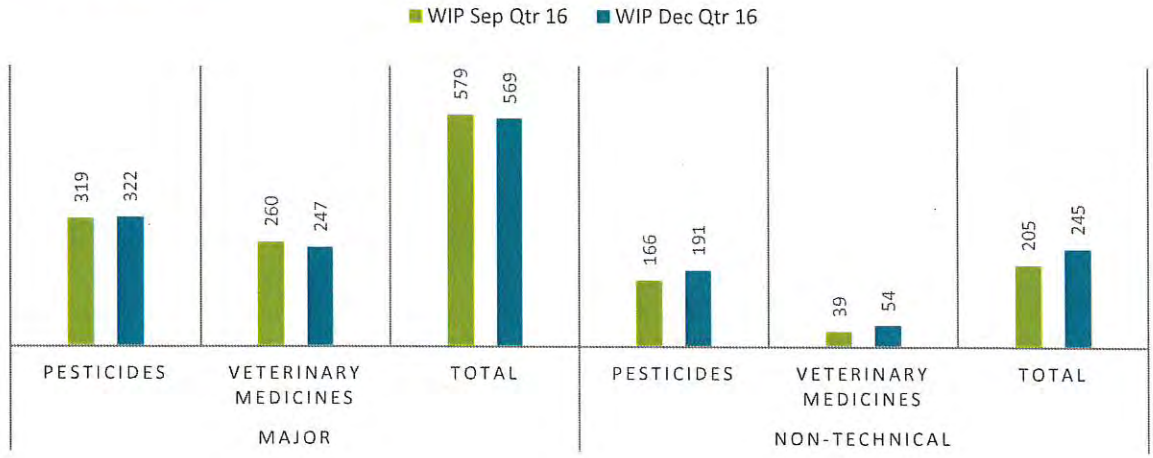
FINALISATIONS



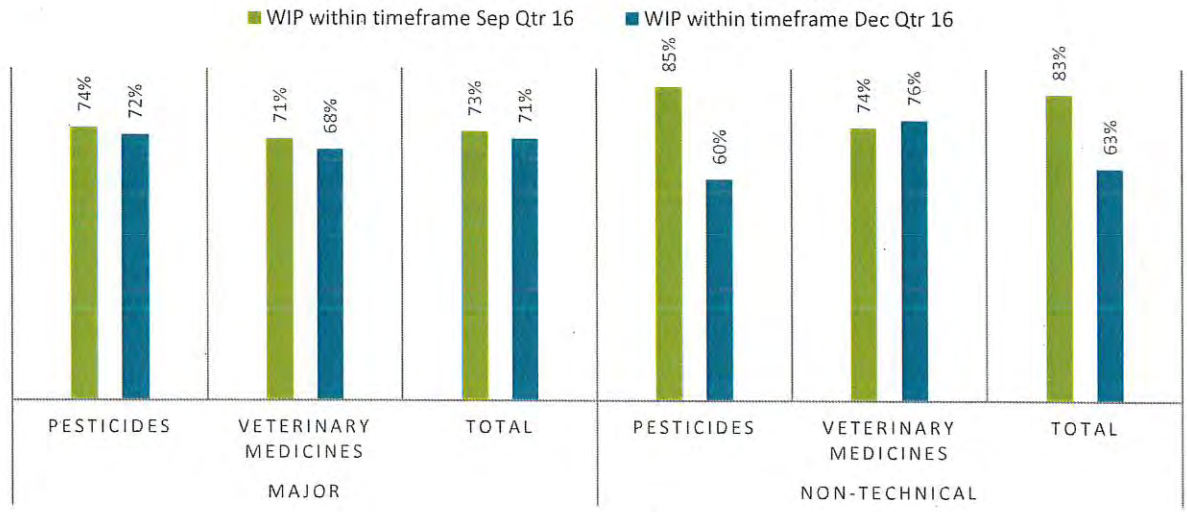
TIMEFRAME PERFORMANCE



WORK IN PROGRESS



WORK IN PROGRESS WITHIN TIMEFRAME



3.2 Applications by item number

ALL APPLICATIONS

Type of application		Item	DECEMBER QUARTER 2016			
			Commenced	Finalised	In progress	Finalised within timeframe (%)
Products	New product/active (new active)	1	0	2	5	0%
		2	4	19	71	47%
	New product (existing active)	3	0	1	1	0%
		4	0	0	0	N/A
		5	5	4	32	75%
		6	7	4	33	0%
		7	48	35	88	37%
		8	26	27	45	78%
		9	0	0	0	N/A
		10	41	44	247	39%
		10A	6	10	3	60%
	Variations	11	0	0	0	N/A
		12	67	37	101	57%
		13	1	3	2	100%
		13A	83	82	7	100%
		14	45	52	204	83%
Actives		15	0	0	1	N/A
		16	1	0	2	N/A
		17	202	157	272	90%
		18	7	39	20	92%
Permits		19	5	4	2	100%
		20	50	44	30	95%
		21	41	28	106	54%
		22	14	20	3	95%
		23	21	13	30	85%
		112A	2	1	1	0%
Other		24	0	0	0	N/A
Time-shift		27	0	3	16	67%
Ingredient determination		28	0	0	0	N/A
Total			676	629	1321	78%

PESTICIDE APPLICATIONS

Type of application		Item	DECEMBER QUARTER 2016			
			Commenced	Finalised	In progress	Finalised within timeframe (%)
Products	New product/active (new active)	1	0	2	3	0%
		2	1	2	14	0%
	New product (existing active)	3	0	1	1	0%
		4	0	0	0	N/A
		5	5	4	27	75%
		6	1	2	9	0%
		7	40	32	70	38%
		8	23	20	41	70%
		9	0	0	0	N/A
		10	31	32	166	44%
		10A	6	8	3	50%
	Variations	11	0	0	0	N/A
		12	45	29	77	48%
		13	0	3	1	100%
		13A	0	0	0	N/A
		14	27	19	102	63%
Permits		19	1	0	1	N/A
		20	40	29	27	93%
		21	36	27	96	52%
		22	12	16	3	94%
		23	13	5	21	100%
		112A	2	1	1	0%
Other		24	0	0	0	N/A
Time-shift		27	0	2	9	100%
Ingredient determination		28	0	0	0	N/A
Total			283	234	672	59%

VETERINARY MEDICINE APPLICATIONS

Type of application		Item	DECEMBER QUARTER 2016			
			Commenced	Finalised	In progress	Finalised within timeframe (%)
Products	New product/active (new active)	1	0	0	0	N/A
		2	1	12	35	58%
	New product (existing active)	3	0	0	0	N/A
		4	0	0	0	N/A
		5	0	0	5	N/A
		6	6	2	24	0%
		7	8	3	18	33%
		8	3	7	4	100%
		9	0	0	0	N/A
		10	10	12	81	25%
		10A	0	2	0	100%
	Variations	11	0	0	0	N/A
		12	22	8	24	88%
		13	1	0	1	N/A
		13A	83	82	7	100%
		14	18	33	102	94%
Permits		19	4	4	1	100%
		20	10	15	3	100%
		21	5	1	10	100%
		22	2	4	0	100%
		23	8	8	9	75%
		112A	0	0	0	N/A
Other		24	0	0	0	N/A
Time-shift		27	0	0	0	N/A
Ingredient determination		28	0	0	0	N/A
Total			181	193	324	88%

3.3 Average decision time

The average decision time remained steady in December quarter 2016 for both standard and extended timeframe applications.

See the notes at the end of this section for information about the tables.

ALL APPLICATIONS - POST 1 JULY 2014

Type of application		Item	DECEMBER QUARTER 2016					
			Standard applications (months)			Extended applications (months)		
			Number Finalised	Average Duration	Assessment Period	Number Finalised	Average Duration	Assessment period
Products	New product (new active)	1	N/A	N/A	18.0	N/A	N/A	25.0
		2	4	18.4	16.7	9	19.4	21.5
	New product (existing active)	3	N/A	N/A	18.0	N/A	N/A	25.0
		4	N/A	N/A	18.0	N/A	N/A	25.0
		5	3	9.9	8.0	1	12.0	12.0
		6	1	15.0	8.0	1	17.5	12.0
		7	29	3.7	3.0	5	8.0	5.0
		8	24	2.6	3.0	3	6.4	5.0
		9	N/A	N/A	2.0	N/A	N/A	4.0
		10	21	9.5	7.3	17	14.1	11.8
		10A	10	2.4	2.0	N/A	N/A	0.0
	Variations	11	N/A	N/A	10.0	N/A	N/A	15.0
		12	34	3.2	3.0	3	5.5	5.0
		13	3	2.5	3.0	N/A	N/A	5.0
		13A	82	0.6	1.0	N/A	N/A	NA
		14	24	6.7	6.9	27	9.1	9.5
Actives		15	N/A	N/A	14.0	N/A	N/A	20.0
		16	N/A	N/A	9.0	N/A	N/A	13.0
		17	145	4.8	7.0	10	8.5	11.0
		18	38	5.8	7.0	1	9.2	11.0
Permits		19	4	1.2	3.0	N/A	N/A	5.0
		20	43	1.9	3.0	1	4.8	5.0
		21	23	6.5	5.1	5	11.3	10.4
		22	19	0.9	3.8	1	7.0	15.0
		23	9	2.3	3.9	4	12.1	12.4
		112A	1	0.3	0.0	N/A	N/A	0.0
TOTAL			517	3.9	N/A	88	11.1	N/A

PESTICIDE APPLICATIONS - POST 1 JULY 2014

Type of application		Item	DECEMBER QUARTER 2016					
			Standard applications (months)			Extended applications (months)		
			Number Finalised	Average Duration	Assessment Period	Number Finalised	Average Duration	Assessment period
Products	New product (new active)	1	N/A	N/A	18.0	N/A	N/A	25.0
		2	N/A	N/A	0.0	1	18.3	14.1
	New product (existing active)	3	N/A	N/A	18.0	N/A	N/A	25.0
		4	N/A	N/A	18.0	N/A	N/A	25.0
		5	3	9.9	8.0	1	12.0	12.0
		6	1	15.0	8.0	1	17.5	12.0
		7	28	3.7	3.0	4	7.6	5.0
		8	17	2.8	3.0	3	6.4	5.0
		9	N/A	N/A	2.0	N/A	N/A	4.0
		10	16	8.0	6.9	12	13.6	11.0
		10A	8	2.5	2.0	N/A	N/A	0.0
	Variations	11	N/A	N/A	10.0	N/A	N/A	15.0
		12	26	3.4	3.0	3	5.5	5.0
		13	3	2.5	3.0	N/A	N/A	5.0
		13A	N/A	N/A	1.0	N/A	N/A	NA
		14	11	7.3	6.6	8	12.7	12.0
Permits		19	N/A	N/A	3.0	N/A	N/A	5.0
		20	28	2.0	3.0	1	4.8	5.0
		21	22	6.7	4.6	5	11.3	10.4
		22	15	1.0	3.6	1	7.0	15.0
		23	4	2.2	4.8	1	15.3	16.0
		112A	1	0.3	0.0	N/A	N/A	0.0
TOTAL			184	4.1	NA	42	11.6	NA

VETERINARY MEDICINE APPLICATIONS - POST 1 JULY 2014

Type of application		Item	DECEMBER QUARTER 2016					
			Standard applications (months)			Extended applications (months)		
			Number Finalised	Average Duration	Assessment Period	Number Finalised	Average Duration	Assessment period
Products	New product (new active)	1	N/A	N/A	18.0	N/A	N/A	25.0
		2	1	3.9	16.9	6	19.8	23.0
	New product (existing active)	3	N/A	N/A	18.0	N/A	N/A	25.0
		4	N/A	N/A	18.0	N/A	N/A	25.0
		5	N/A	N/A	8.0	N/A	N/A	12.0
		6	N/A	N/A	8.0	N/A	N/A	12.0
		7	1	3.0	3.0	1	9.7	5.0
		8	7	2.3	3.0	N/A	N/A	5.0
		9	N/A	N/A	2.0	N/A	N/A	4.0
		10	5	14.4	8.6	5	15.4	13.8
		10A	2	2.0	2.0	N/A	N/A	0.0
	Variations	11	N/A	N/A	10.0	N/A	N/A	15.0
		12	8	2.4	3.0	N/A	N/A	5.0
		13	N/A	N/A	3.0	N/A	N/A	5.0
		13A	82	0.6	1.0	N/A	N/A	NA
		14	13	6.3	7.2	19	7.6	8.5
Permits		19	4	1.2	3.0	N/A	N/A	5.0
		20	15	1.7	3.0	N/A	N/A	5.0
		21	1	1.8	16.0	N/A	N/A	0.0
		22	4	0.7	4.5	N/A	N/A	0.0
		23	5	2.3	3.2	3	11.1	11.2
		112A	N/A	N/A	N/A	N/A	N/A	N/A
TOTAL			148	2.0	NA	34	11.2	NA

Table notes

Average decision time is the average time taken to complete evaluations from commencement to finalisation. Average time is calculated by adding the decision times and dividing these by the number of applications in that category. Decision time is calculated by subtracting the commencement date from the finalisation date and dividing by 30.417 to get the decision time in months.

The assessment period for each application type and item number is set in the legislation—this is the standard decision time. However, there are two conditions which allow the APVMA to vary or extend the assessment period:

- a change in the category of an application may be made once in the life of the application under section 70(b) of the Agvet Code
- one extension of 1.33 times the original assessment period (rounded up) plus one month may be applied for under section 159 of the Agvet Code

N/A means no applications were finalised for that item in the reporting period.

Variable means some items have a variable legislated assessment period because they are modular in nature. Each application will have a different expected duration. The figure in brackets after the variable text show the average expected timeframe for these items in this quarter. This average expected timeframe may change in each quarter depending on the nature of the applications being evaluated.

4 OTHER REGULATORY FUNCTIONS

4.1 Internal reviews

The APVMA had 3 internal reviews due in the December quarter 2016.

INTERNAL REVIEWS – DECEMBER QUARTER 2016

Quarter	Decision Due	Finalised	Finalised within timeframe (%)
Sep 16	1	0	0
Dec 16	3	0	0
Total	3	0	0

If an applicant is not satisfied with a decision made by the APVMA an internal review can be requested. These must be completed within 90 days.

4.2 Chemical reviews

The reconsideration of approvals and registrations of omethoate was completed in December 2016, bringing the number of reviews currently in progress down to 16.

In October 2016, dimethoate component reports (supplementary toxicology report; re-entry update to occupational health and safety report) and proposed regulatory decision report were published for consultation for a period of three months.

Paraquat toxicology report (3 volumes, includes neurotoxicology) was also published in October 2016

A chemical review or 'chemical reconsideration' is where the APVMA reconsiders the registration of a chemical, if risks to safety and performance have been identified.

4.3 GMP audit program

In the December quarter 2016, the APVMA completed 27 good manufacturing practice (GMP) audits—19 in Australia and 8 overseas – with 92.6 per cent of GMP audits completed within timeframe.

GMP ACTIVITY – DECEMBER QUARTER 2016

Quarter	Audit location	Number completed	Within timeframe	Within one week of due date
1	Australia	19	94.7%	94.7%
	Overseas	8	87.5%	87.5%
2	Australia	16	87.5%	100%
	Overseas	5	80%	100%
Total		35	89.6%	95.8%

Good Manufacturing Practice (GMP) is part of quality assurance in the manufacturing process and relates to both production and quality control.

4.4 Compliance statutory notices

The APVMA issued one stop supply notice in the December quarter 2016.

NOTICES ISSUED – DECEMBER QUARTER 2016

Quarter	Issued	Finalised	Within timeframe
Sep 16	0	0	N/A
Dec 16	1	0*	100%
Total	1	0	100%

* Decision stayed by Administrative Appeals Tribunal

Compliance statutory notices are formal correspondence from the APVMA under the agvet code and include: stop supply or recall notices or substantiation notices. Notices are issued periodically throughout the year and must be published within 14 days.

5 2016-17 YEAR TO DATE PERFORMANCE OVERVIEW

Between 01 July and 31 December 2016, the APVMA:

- finalised 76 applications for pre-application assistance
- received 1219 new product, active and permit applications for preliminary assessment
- commenced assessment/evaluation of 1340 product, active and permit applications
- finalised 1224 product, active and permit applications
- overall timeframe performance was 77% for product, active and permit applications types with:
    - 67 per cent of applications for pesticides completed in timeframe
    - 85 per cent of applications for veterinary medicines completed in timeframe
    - 75 per cent of applications for actives completed in timeframe
    - 81 per cent of applications for permits completed in timeframe
- 74 per cent of the 1321 applications in progress are within timeframe
- 57 per cent of applications requiring major assessment for pesticides were completed within timeframe
- 68 per cent of applications requiring major assessment for veterinary medicines were completed within timeframe
- 74 per cent of non-technical applications for pesticides were completed within timeframe
- 98 per cent of non-technical applications for veterinary medicines were completed within timeframe

SUMMARY OF ACTIVITIES RELATED TO REGULATORY DECISIONS JULY–DECEMBER 2016

Types of regulatory decisions*	Commenced	Finalised/issued	In progress
Pre-application assistance	71	76	37
Product registration—pesticides	443	333	524
Product registration—veterinary medicines	308	318	326
Actives	351	328	300
Permits	238	245	171
Items 8L, 8M, 8P	127	150	10
Item 25	8	6	16
Notifiable variations	355	221	84
Import consents	260	256	0
Certificates of export	154	159	10
Total	2315	2092	1478

*See description of application types.

6 GLOSSARY OF TERMS

Product applications – applications made for the registration of pesticides (substances or mixtures of substance intended for preventing, destroying, repelling or mitigating any pest) and veterinary medicines (substances or mixtures of substances intended for treating diseases or conditions in animals). Product applications include applications within item numbers 1–14. It excludes notifiable variations and items 8L, 8P, 8M and 25.

Major assessments have assessment periods over three months and require one or more technical assessments. Includes item numbers 1, 2, 3, 4, 5, 6, 10, 11 and 14.

Non-technical assessments have assessment periods of three months or less and have no technical assessment. Includes item numbers 7, 8, 9, 10A, 12, 13 and 13A.

Actives – the component of a pesticide or veterinary medicine product that is responsible for its physiological or pharmacological action. Applications for active constituents are covered under items 15–18, plus a number of applications in items 1 and 2.

Permits – applications to use or possess an unregistered pesticide or veterinary medicine or for an off-label use of a registered pesticide or veterinary medicine. Covers items 19–23.

8L, 8M and 8P – applications to either change the holder or nominated agent of an approval or registration or nominate a nominated agent for an approval or registration

Item 25 – are technical assessments used to determine that a data package addresses the safety, efficacy and trade criteria. An outcome of a technical assessment can be used by an applicant as part of a future application.

Notifiable variations – minor change to the details of a registered product, actives or labels without having to register a new product. This process commenced on 1 January 2015. There is no statutory timeframe for the APVMA to process these, they are considered to be accepted upon lodgement by the applicant after some checks of the information.

Import consents – consents to import are permits that allow unregistered or unapproved chemicals into Australia when a legitimate reason exists for a person or company to have possession of the chemicals in Australia, eg for research, chemical trials or special veterinary applications in zoos. There is no statutory timeframe for the APVMA to process these but the APVMA aims to process import consents within 14 days.

Certificates of export – before accepting exports of a chemical product from Australia, many countries require an assurance from the government authority responsible for regulating the product in Australia. This is provided by the APVMA in the form of a certificate of export. There are no statutory timeframes for the APVMA to process these.

Australian Government

Australian Pesticides and
Veterinary Medicines Authority

NOVEMBER 2016

APVMA in Armidale: Relocation Strategy

BUILDING A WORLD CLASS
REGULATOR IN REGIONAL AUSTRALIA

CONTENTS

1 BACKGROUND

The government is developing a Centre of Agricultural Excellence at the University of New England to drive growth in agricultural productivity and deliver substantial economic benefits to regional Australia, noting that the Australian Pesticides and Veterinary Medicines Authority (APVMA) will be part of that Centre of Excellence.

This relocation strategy outlines the broad activities needed to efficiently transfer APVMA functions from Canberra to Armidale. This relocation strategy is focussed on what needs to happen to move the APVMA, while minimising potential adverse issues during the transition, and to maximise capacity when it operates from Armidale. The detailed planning and scheduling of a transition will be carried out during Phase 1 of the project.

An overview of the APVMA is at Attachment A.

1.1 Objectives for the relocation

There are four key objectives for the APVMA during the relocation:

1. Retain access to as much specialist expertise as possible, particularly regulatory scientists
2. Minimise the impact on the ability (in terms of capacity and capability) to meet legislative obligations in the lead up to, during and after the relocation
3. Maintain stakeholder access to the APVMA
4. Ensure APVMA staff and their families are treated with respect and assisted through the relocation, regardless of their choices.

These objectives are the based on the most significant risks to the agency in relation to the relocation and consideration of these objectives forms the basis of the strategies and timeframes contained in this strategy.

1.2 Underlying assumptions

There are a number of factors which form the underlying assumptions of the relocation strategy:

1. Based on previous staff surveys, only 10-15 per cent of current staff have indicated they may consider relocating to Armidale, with less than 10 (out of 100) regulatory scientists saying they will move.
2. There is no pre-existing building in Armidale to accommodate the APVMA and a new premises is required.

What is a regulatory scientist?

Regulatory science involves a pragmatic application of scientific methods for the purpose of making a decision within a defined legislative framework and timeframe about whether to allow something (eg chemicals) to be used.

Conventional science involves the application of scientific methods to understand some physical, chemical or biological phenomena. It tends to be curiosity driven, forward looking and speculative.

What differentiates regulatory science from conventional science is that decisions are based on analysis and interpretation of existing scientific knowledge and, where necessary, assumptions to address data gaps or uncertainty. Regulatory scientists do not generate new lines of enquiry to answer questions, instead relying on available information to make a decision.

While regulatory science incorporates a variety of scientific disciplines, it is in itself a specialised field of science. As well as holding conventional scientific qualifications, regulatory scientists are trained in risk analysis, public administration and regulatory decision making.

Most regulatory science training is done on-the-job as there are currently no formal courses in regulatory science and it tends to be specific to legislative frameworks.

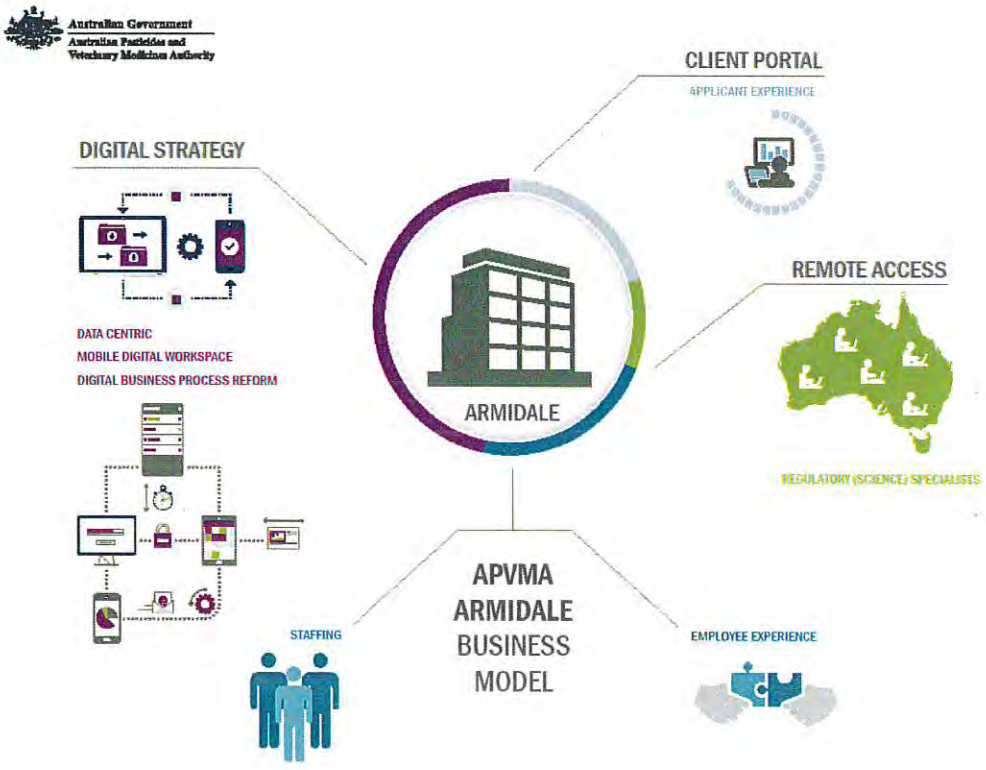
2 HOW APVMA WILL OPERATE FROM ARMIDALE

2.1 Building on the foundations

The APVMA is the national regulator of agricultural and veterinary (agvet) chemicals. Registering agvet chemicals relies on a team of highly qualified regulatory scientists, legal experts and case managers, all supported by specialist compliance and licensing teams and a strong corporate team. The APVMA began its move into the digital world in 2014 with the introduction of full on-line submission of applications by industry.

As part of building a world class regulator in regional Australia, the APVMA will:

- establish a network of regulatory scientists working both remotely and in Armidale
- develop a modern and collaborative workspace in Armidale that can showcase the next generation of public sector operations from regional Australia
- take the client experience to the next level by embracing a full on-line experience for applicants
- implement a new digital strategy to enable the APVMA to work effectively in this new business model.



2.2 Virtual network of regulatory scientists

Suitably qualified regulatory scientists are in short supply and it takes time to train them to be fully functional. Continued access to these regulatory specialists is one of the highest risks associated with the relocation. The priority, therefore, is to implement a new way of working through a 'virtual science network' to maintain access to the skills needed.

With such a network, regulatory scientists would work remotely from anywhere in Australia, but still be connected to the Armidale office through a new digital strategy. This means the APVMA will not be constrained by availability of scientists in Armidale.

2.3 Regulatory hub in Armidale

The APVMA handles over 5000 applications every year. The office in Armidale will embody the flexible team-based approach taken by the APVMA to handle so many applications with around 200 staff. There will be a call centre and case management hub to service clients; collaborative space to enable people to come together to work on applications – even if people are working remotely; and technology enabled facilities with virtual meeting rooms. This infrastructure will also make it easier to work with our regulatory counterparts in other countries. The facility will be modern and provide a quality employee experience – acting as an inducement for staff to move to Armidale.

The CEO, executive, key management roles and staff from case management, call centre, application administration, corporate, legal, licensing and compliance will be based in Armidale, along with those regulatory scientists wishing to be located in Armidale. While many regulatory scientists will be operating remotely, the scientific leadership will be based in Armidale. Over time, the APVMA will build networks with universities to bring through the next wave of regulatory specialists through the system.

The initial target will be 100 people operating out of Armidale, building up to 150 over time.

2.4 Client service in a digital world

The APVMA will enhance its online client experience by making it easier for applicants to submit data underpinning an application. This will be done by implementing internationally agreed standards for electronic submission of data (where possible), expanding the functionality of the client portal to enable full tracking of applications and improving on-line communication and correspondence with the APVMA.

The APVMA will enhance its capability to conduct web conferencing with clients, regardless of where they are in the world. The APVMA also recognises that some clients still want to discuss their applications face to face – to save client travel expenses, the APVMA will trial 'surgeries' in Sydney and Melbourne. The APVMA will also provide the option for applicants to meet in the Armidale office.

2.5 Taking advantage of digital opportunities

A digital strategy that underpins innovation in public sector administration and regulation is a critical component of making the APVMA a more contemporary agency – and a showcase for how other public sector agencies can operate from regional locations. A well planned digital strategy will deliver:

- *'data-centricity'* – data will be stored in a single repository (according to agreed standards), with easy access by those needing to use the data and strong data governance
- *'mobile digital workplace'* – strong enterprise connectivity, whether in the office or working remotely, streamlined business processes and enhanced workflow management, tracking and reporting
- *'digital business platform'* – one platform with interconnected business channels for faster processing time and greater accuracy, with 'touch points' automated as much as possible.

This strategy is a critical and necessary prerequisite for the APVMA to operate from Armidale and still retain access to the specialist skills it needs to perform its functions.

2.6 Full online workflow management

The APVMA will introduce a full workflow management system to underpin its virtual workforce. This system will automate repetitive tasks, remove 'human error' in processing applications and allow the assignment and tracking of tasks. Such a system will also incorporate the APVMA's compliance and licensing functions, thereby creating an integrated end-to-end regulatory system.

This approach will improve efficiency and productivity, allow the regulatory scientists to focus on science rather than administration and help manage a dispersed and mobile workforce.

- **Staff** will be able to login and easily see what tasks they have to perform and by when – no matter where they are. They will have full access to the information and data they need to complete their work and automated notices for communicating with clients, without the need for paper files or manual data entry.
- **Managers** will be able to assign tasks and track progress, to ensure all the elements come together to form a registration decision within legislative timeframes.
- **Clients** will be able to submit applications and all required information and data and see exactly where their application is up to through a linkage to the client portal.

3 KEY ELEMENTS OF THE RELOCATION

In designing a move of an agency like the APVMA, which relies heavily on highly specialised staff and has a range of legislative obligations, there are several factors to be taken into account, covering:

- **Business model** – to outline in detail how the APVMA will operate in Armidale, including a draft structure so staff can identify where they will fit in a future organisation, including which positions will be eligible for remote working arrangements
- **Staffing strategies** – to retain as much of the current workforce as possible in the lead up to the relocation and to operate from Armidale, and to recruit suitable people to sustain the organisation
- **Knowledge management** – to capture the corporate knowledge of people leaving the agency and to train new people as quickly as possible
- **Digital strategy** – to develop tools and platforms to support a highly networked and technology based agency
- **Change management** – to ensure staff are supported through the transition
- **Risk management and business continuity** – to ensure strategic and operational risks are identified and mitigation strategies developed and tracked
- **Financial management** – to ensure the APVMA has sufficient resources to conduct 'business as usual' and manage a success transition to Armidale with a cost structure and fee arrangements that reflect the new business model
- **Stakeholder management and engagement** – to ensure stakeholders fully understand what is happening and that transition planning takes into account stakeholder needs
- **Communication** – to maintain trust and confidence in the APVMA and to support APVMA staff and their families through the transition
- **Transition planning and logistics** – to ensure the various components of the relocation come together seamlessly to maximise the success of the transition.

3.1 Business Model Finalisation

The business model for APVMA's operation from Armidale will be finalised, including a new management structure against which recruitment and staff placement will occur. The business model will identify key business processes and how they will be performed by the APVMA. A draft structure for Armidale will be developing, including detailing those positions which will be located in Armidale and those which may be eligible to operate remotely.

3.2 Staffing Strategies

Retention

Given about 10-15 per cent of current staff are expected to move to Armidale, an attractive retention package will be provided to retain as many staff as possible until the Canberra office closes to ensure business continuity, contribute to the design and implementation of the revised business model and digital strategy, train new recruits and ensure appropriate knowledge transfer is undertaken.

Recruitment and workforce planning

A workforce plan, coupled with a recruitment strategy, will be developed to deliver on the agreed business model for Armidale. There will be two phases – ensuring there is sufficient capacity to operate from Canberra in the short term and the longer term strategies to operate from Armidale.

In the short term, rolling recruitment arrangements have been implemented to ensure there is a pool of potential employees to draw upon as people leave the agency. Employment agencies have been engaged and networks are being used to identify potential short term employees. Contractors and consultants are also being used where possible and appropriate.

Longer term, it is anticipated that the majority of case management, administration and corporate positions will be drawn from the Armidale region.

More specific comments about specific groups of employees are outlined below.

Regulatory Scientists

APVMA has around 100 regulatory scientists across a range of scientific disciplines. A major focus of workforce strategies for this group will be on retaining access to existing skilled staff in the long term and recruiting new staff to fill gaps in capacity and capability both during and after the transition.

Regulatory scientists have highly specialised skills that are in short supply in Australia – recruitment is difficult even in Canberra. Most regulatory scientists exist in government (typically in regulators like the TGA, NICNAS and FSANZ), with some in industry. It takes between two to five years to train a regulatory scientist (on top of their university degree) to assess applications and make appropriate recommendations against the legislation. The decision makers, or delegates, are executive level officers who typically have seven to ten years experience.

There are four core elements to the strategy to maintain access to suitably skilled regulatory scientists:

1. Provide additional incentives for regulatory scientists to move to Armidale.
2. Establish mechanisms for regulatory scientists to work remotely (from home) if they do not move to Armidale.
3. Provide incentives for regulatory scientists who intend to retire or transfer to other employment opportunities in Canberra to stay at the APVMA until the relocation occurs to train new recruits and/or continue undertaking assessments.
4. Establish ways to source regulatory expertise from now until the APVMA is fully operational in Armidale.

Case Management and Administration

The Case Management and Administration (CMAU) team is responsible for the main interface with the public and applicants. CMAU undertakes preliminary assessment of applications, does all the administration relating to issuing of notices and finalisation of applications and handles enquiries from clients and the public. It is a critical function involving considerable corporate knowledge. Very few of the current CMAU group are likely to go to Armidale. These staff would be easily able to find similar roles in Canberra. In the long run, it is expected that the majority of this team would be recruited from the Armidale region.

In addition to providing incentives for existing case management staff to stay with the APVMA while in Canberra, a significant focus will be the process of recruiting and training Armidale based staff. It is expected this process will begin six months out from the Armidale office opening, with team leaders brought to Canberra for three months training. Three months out, the rest of the team and training 'centre' will be established in Armidale, where current staff will upskill the team prior to 'going live' from the new premises.

Corporate

Corporate functions include: HR, finance, communications and IT. It is expected that the majority of staff will be recruited from the Armidale region. The recruitment strategy will focus on having full teams in place from the time of opening in Armidale, ensuring sufficient time is incorporated for training and knowledge transfer. Contracting out key services (for example IT and payroll) will be investigated to either fill potential expertise gaps or create efficiencies.

Legal and compliance

The APVMA has a range of specialist staff in compliance, licensing and legal roles whose expertise has been built up over many years. While the preference would be for these teams to work out of Armidale, there may be a need to provide remote operational capability as a transition measure. A flexible approach to resourcing these functions will be taken and will be dependent on the expertise of the people who will transfer to Armidale and potential gaps that may arise. Outsourcing of legal advice will also be investigated.

Redundancy, redeployment and retirement

A large number of staff are expected to take a redundancy package and staff have requested information on provisions as soon as possible so they can make long term decisions. The redundancy provisions will be finalised during the enterprise agreement negotiations and will be standard once the agreement is in place. Assistance with financial advice will be provided to all staff and a package of assistance for staff leaving the APVMA will be provided (for example, training and job search assistance). Other staff have indicated a desire to be redeployed or to retire. Policies for these aspects will be developed.

Relocation incentives

A range of incentives will be provided to encourage people to relocate to Armidale. A draft policy will be circulated as soon as possible after the GPO is issued to help staff begin the process of making a decision about their future. Incentives will include salary loading, relocation assistance and return trips to Canberra for the first 12 months.

Worker health and safety

A significant component of the new business model is the ability to work remotely. There are a range of worker health and safety obligations and expenses involved with these arrangements. A specialist work health and safety officer with experience in remote working arrangements will be employed to establish the necessary policies and procedures and ensure appropriate systems are developed and implemented.

The health and resilience of Canberra based staff in the lead up to relocation will be a high priority. Specialist consultants will be employed to implement programs to support staff during the transition. A staff liaison officer will be employed as part of the transition team.

3.3 Knowledge transfer

Half of the current APVMA regulatory scientists have over eight years of experience. While the APVMA has a framework of work instructions, this is not sufficient to compensate for the potential loss of knowledge possessed by staff, built up over many years. There is also a need to transfer knowledge of non-scientific staff to minimise disruption to the running of the organisation and interactions with clients. A knowledge management strategy (including mentoring, training and documentation) will be developed and implemented, noting that additional staff may need to be employed to ensure business continuity while others are off-line to undertake activities for knowledge transfer.

3.4 Digital strategy

The APVMA is required to have applications submitted electronically. This requirement has implications for both internal and external portals for the electronic handling of submissions. Due to the very short timeframes to implement the legislation in 2014 and the online requirements, priority was given to functionality for applicants to submit their applications electronically. Work on the internal systems to effectively operate a paperless system (as opposed to the previous file based system) was deferred.

The transformation from paper to electronic was a major exercise – with considerable work still underway to move off multiple legacy systems. As a result, there is still a need for a number of manual 'work arounds' and staff rely heavily on face to face interactions to do their work. The current system is not fit for purpose for a more collaborative networked model that supports staff working remotely with access to a single source of data.

A new digital strategy is a critical component for APVMA to successfully operate from Armidale. The strategy will cover how the APVMA can be:

- **Data centric** – given data is an important asset for the APVMA, the focus will be on managing data through a controlled, verified and managed single source of truth, with full data integration and analytical functionality.
- **A fully mobile digital workplace** – where corporate systems and information can be securely accessed anywhere, anytime from a variety of devices, with full on-line and intuitive collaboration tools for staff and clients.
- **Streamlined and automated** – with a single end to end online service with digital workflow control and automated 'touch points' and minimal data entry.

The APVMA is currently undertaking an extensive business process review to identify process improvements and processes that can be automated. This work will be critical to informing the business requirements for a digital strategy. The work has the added benefit in that it will reduce the administrative burden faced by APVMA staff, leading to increased capacity to undertake scientific assessment and regulatory decision making.

A high priority will be to engage a digital partner to prepare a detailed proposal (with costings) for consideration by government (in the first half of 2017) and to build and implement a new system. Given the time it will take to design, build and test a new IT system, no major changes will be able to be accommodated to the system specifications once they are locked down in 2017. The APVMA will work closely with the Department of Agriculture and Water Resources to ensure the core elements of the future reform package are included in the specifications process. Further reform may need to be delayed until after the relocation has been completed.

3.5 Change management

Relocation of the APVMA to Armidale is a significant change management exercise with many facets, including supporting staff during the transition, implementing a revised business model and digital strategy, integrating the APVMA into the Armidale community and helping stakeholders and the broader community understand what is happening. A major focus will be on staff and organisational resilience during the transition.

3.6 Risk management and business continuity

The development and transition to a new business model for the APVMA operating out of Armidale will be a complex task. Identifying risks and mitigation strategies will be a critical part of the planning phase and mechanisms will be embedded to continually analyse and update the risk framework. A specialist risk management position will be established as part of the transition team and the stakeholder advisory committee will have an important oversight role in this area.

There is a high risk of impacts on business continuity throughout the transition period from anticipated staff departures (particularly the possibility of losing highly skilled and experienced staff), the lengthy time it takes to train new starters, and the re-tasking of existing staff to support critical work underpinning the transition. The impact on the quality and timeliness of decision making will be carefully monitored. Options for alerting applicants and industry to potential delays will be identified alongside the development of criteria for prioritising applications for assessment when capacity and capability issues arise.

3.7 Financial management and reporting

The APVMA will have three main funding sources over the next few years – the fees and levies paid by applicants, relocation funding and Agricultural Competitiveness White Paper funding (for reform activities). Systems will need to be established to manage and report against these budgets. A new financial model will need to be developed to align with the new business model and the related cost structures. In the interim, cash flow will need to be monitored carefully if there is a drop off in applications coming through the system (given the core activities of the agency are fully funded by industry).

3.8 Stakeholder management and engagement

Effective stakeholder management will be a critical component of the relocation with the need to:

- identify options for how clients can meet with the APVMA in a cost-effective way (for example, through digital means or regular APVMA 'surgeries' in Sydney and Melbourne – to save companies travelling to Armidale)

- develop mechanisms for clients to easily track the progress of their application, given that delays are expected to occur in the lead up to, during and immediately after the relocation.

Some stakeholders will play an important role in designing the future business model and advising on various elements of the relocation. An APVMA Relocation Advisory Committee (ARAC) will be established by the APVMA CEO to provide strategic advice on major aspects of the relocation and the transition of the APVMA from Canberra to Armidale.

The roles of ARAC will include:

- assisting with the design of the business model for the APVMA operating out of Armidale
- providing input to the design and delivery of the digital strategy to underpin the Armidale business model
- identifying strategic risks and advice on mitigation strategies related to the relocation of the APVMA
- identifying relocation related stakeholder issues and advice on engagement and communication activities and issues management (as appropriate)
- providing high level oversight of the progress against key milestones
- considering other relevant issues referred to ARAC by the APVMA CEO.

ARAC will not be a decision making body and will not have any direct say on the day-to-day management of the relocation project or the allocation of resources. Members will be sourced from government, industry and the Armidale community. ARAC will meet monthly and will provide regular updates to government and stakeholders.

3.9 Communications

A communication strategy will be implemented to help manage staff, stakeholder and government expectations of the APVMA during the transition as well as associated media and issues management. A specialist firm has been engaged to manage the initial phases of the communication strategy. The focus of the initial phase (once the announcement has been made) will be:

- repositioning the conversation about the relocation to focus on the ongoing role of the regulator rather than the current focus on the actual decision
- to maintain confidence and trust in the APVMA by staff, stakeholders and government
- messaging to encourage staff to stay at the APVMA
- ways to ensure engagement of staff and stakeholders in the various aspects of the relocation
- an Armidale campaign for staff and their families to get to know Armidale and for the Armidale community to get to know the APVMA.

3.10 Transition planning and logistics

The APVMA is a fully cost recovered agency with skills in registering agvet chemicals. It does not have the skills or resources to plan and execute a relocation of this magnitude. The priority is to augment the current corporate team with staff or external consultants with specialist skills in property, project management/scheduling, community liaison, change management, risk management, governance, finance, HR and communications.

The relocation will be led by the **Chief Operating Officer** (COO). The COO will oversee all corporate and relocation related services to ensure the relocation happens with as minimal disruption as possible to services to support business as usual.

Two new senior positions will be established to support the COO:

- **Relocation Operations Manager** – responsible for the overall planning, scheduling and delivery of the logistics of the relocation (including property related matters), as well as ensuring appropriate risk management, procurement, governance, record keeping and staff liaison arrangements are in place.
- **Digital Strategy Executive Director** – responsible for ensuring the digital strategy is designed and delivered to underpin the Armidale business model, including overseeing linkages to 'business as usual' systems and the new digital strategy as well as the transition from the existing system to the new system.

External experts will be engaged as appropriate to manage elements of the relocation (including property, communications, IT and business model development). New positions will also be created in the HR and finance teams to support relocation activities. The APVMA Relocation Advisory Committee (ARAC) secretariat will be within the Office of the CEO.

4 INDICATIVE TIMELINES

Relocating an agency the size of the APVMA will require careful planning in order to minimise disruption to staff and applicants. There are many inter-related components covering 'business as usual' activities and the physical relocation of the APVMA which need to be worked through.

There are two major activities that will govern the overall timeframes – the Armidale facility and the digital strategy. At the time of writing, funding for the digital strategy is subject to further government consideration and options for Armidale facilities and the timeframes for the approval and construction of the Armidale building are unknown.

Scheduling experts will be engaged as soon as possible after the GPO is issued to do the detailed planning and mapping. Subject to the caveats above in relation to the digital strategy and accommodation, the following broad timelines are forming the initial basis of planning for the relocation:

Phase 1: Planning (to June 2017)

- Establish transition team
- Finalisation of Armidale business model
- Development of detailed digital strategy, agreed by government
- Decision on Armidale accommodation
- Preparation of detailed transition plan and scheduling
- Establishment of ARAC
- Drafting of staff related policies and ongoing support for staff
- Establishment of physical presence in Armidale

Phase 2: Preparation for Relocation (July 2017 to March 2019)

- Armidale building construction
- Digital build and testing
- (toward end of 2018), staff decisions about moving to Armidale, and finalisation of workforce requirements for Armidale
- Scheduling for physical removal
- Accommodation strategy for Canberra building
- Cost recovery arrangements finalised

Phase 3: Systems testing and site preparation (March 2019 to June 2019)

Assuming Armidale building is ready for occupation

- Final testing of IT systems for use on site and remotely
- Corporate teams move into Armidale to prepare building (for example IT, systems, call centre, information/records)
- Case Management and Administration staff recruited and trained for Armidale (noting teams will need to run concurrently in Canberra and Armidale for a period)

Phase 4: Relocation (from July 2019)

- Final transition of staff to Armidale, remote operating arrangements or transfer/redundancy arrangements.

Phase 5: Windup of Canberra Office (post July 2019)

- Make good of Canberra building
- Implementation of strategy for accommodation until end of lease period.

ATTACHMENT A: ABOUT THE APVMA

The APVMA is the independent statutory authority responsible for assessing and registering pesticides and veterinary medicines proposed for supply and use in Australia.

VISION	Australians have confidence that agricultural and veterinary chemicals are safe to use.
MISSION	To protect the health and safety of Australia – its people, animals and environment – and support Australian agriculture by taking a scientific and risk-based approach to regulating agricultural and veterinary chemicals.

The APVMA is responsible for regulation of agvet chemicals up to the point of their sale. The states and territories are responsible for regulating the use of those chemicals by farmers and other end users.

The key legislative functions of the APVMA are[1]:

- assess the suitability for sale in Australia of active constituents and chemical products and the suitability of labels for the use of those chemical products
- ensure that active constituents, registered chemical products and labels for chemical products comply with the Agvet Code.

The APVMA fulfils these functions by:

- assessing and registering new chemicals, approving new uses for existing registered products and approving changes to existing registered products
- approving labels for registered products
- assessing and approving active constituents for proposed or existing registered products
- issuing permits for minor use, research, emergency use, import and export of agvet chemicals
- reviewing existing chemicals to ensure they are safe to use
- undertaking compliance and engagement activities to ensure products and active constituents available for use comply with the Agvet Code
- managing a licensing scheme for veterinary manufacturers.

These functions are supported by case management of applications and applicants, legal advice and corporate support.

The APVMA handles over 5000 applications every year – a mix of 'major' and 'minor' applications - and has over 11,500 agvet chemicals on the register.

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[1] Functions and powers are conferred on the APVMA by the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemicals Code*.

The APVMA is a Commonwealth Corporate Entity and is nearly fully cost recovered, with approximately 40 per cent from application fees and 60 per cent from industry sales levies. The APVMA collects the levies.

Registration Process

Assessing applications for registration of agvet chemicals comprises the majority of the work of the APVMA. In doing so, a common process is used across the broad range of applications submitted to the APVMA.

In summary:

- Applicants submit applications on-line
- Case Management and Administration officers undertake preliminary assessment and the application passes through to regulatory scientists – noting that everything is electronic (not paper based)
- Regulatory scientists determine what scientific assessments are needed to make a decision and necessary assessments are commissioned (either internally or through external service providers)
- Once assessments are complete, a decision about whether a product can be registered is made
- The Case Management and Administration team does the administrative tasks to finalise the registration and ensure it is on the register.

Other key processes

The APVMA also runs a licensing scheme for veterinary manufacturers. Third party auditors submit reports to the APVMA for consideration and action. Staff within this team have experience in the manufacturing sector and work is underway to move the systems underpinning the licensing scheme to being fully on-line.

The compliance and enforcement team operates a risk based process to assess and respond to reports of non-compliance against agvet legislation. Record keeping systems are in place to ensure any investigations are clearly documented. Compliance staff have been trained in agvet legislation as well as holding compliance specific qualifications.

There is a small in house legal team that provides advice essential to ensuring that APVMA's operations conform to the complex legislative framework under which the APVMA operates

APVMA business improvement activities

The APVMA has a significant program of work underway to improve its regulatory approaches, its efficiency and its services to industry. Specifically:

- Different methods of regulating agvet chemicals of lower regulatory risk (for example through on-line fast track registration, registration against standards and expansion of notifiable variations)
- Increased use of international data, guidelines and assessments
- Increased use of external expertise and a pilot to test the purchase of efficacy assessments by applicants prior to application submission
- Improving the useability of APVMA's on-line offerings for applicants.

Profile

The APVMA staff are employed under the Australian Public Service Act. The APVMA currently has 209 staff, comprised of:

- 103 regulatory scientists
- 13 compliance officers
- 7 manufacturing licensing officers
- 7 specialist legal officers
- 30 case managers and registration support officers
- 40 corporate, including 15 IT officers
- 9 executive and coordination.

All staff are located in Canberra, except for one compliance officer who is out posted in Perth.