

*Australian
Pesticides and
Veterinary
Medicines
Authority*
Review of Cost
Recovery
Arrangements

*Final Report
October 2017*

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Limitations

Our work was limited to that described in this report. It was performed in accordance with PIN 23350 under the terms and conditions of the deed executive in relation to the Australian Customs and Border Protection Services Provider Panel 127074 between PricewaterhouseCoopers and the Department of Agriculture and Water Resources. It did not constitute an ‘audit’ or ‘review’ in accordance with the standards issued by the Auditing and Assurance Standards Board, and accordingly no such assurance under those standards will be provided in this report.

1 Executive Summary

1.1 Introduction

PricewaterhouseCoopers (PwC) was engaged to undertake an independent review of the current cost recovery arrangements in place for the Australian Pesticides and Veterinary Medicines Authority (APVMA or Authority). Through this assessment PwC were also required to provide an overview of the APVMA's financial outcomes over the period 2014-15 through to 2016-17 with a view to identifying any key issues impacting the APVMA's financial position and sustainability.

The Australian Government provides a diverse range of services, support and benefits to the Australian public to achieve its policy outcomes. These activities are funded from different revenue sources, including general taxation, sales of public assets, government investments, cost recovery and other revenue-raising measures. Cost recovery involves the Australian Government charging the non-government sector some or all of the efficient costs of a specific government activity. That activity may include the provision of goods, services or regulation, or a combination of them.

Cost recovery can promote equity, whereby the recipients of a government activity, rather than the general public, bear its costs. An effective arrangement can also influence demand for government activities, improve the efficiency, productivity and responsiveness of government activities and accountability for those activities. A robust and transparent cost recovery model can also increase cost consciousness for all stakeholders by raising awareness of how much a government activity costs. The scope and approach of this review are included in **Appendix A**.

1.2 Overall observations

The review identified a number of issues that are currently contributing to the APVMAs financial position and ongoing sustainability. The most significant of these issues are resulting from the time taken to undertake a comprehensive cost recovery review of its arrangements and to update them as necessary. There is a significant imbalance between revenue and expense which is forecasted to grow if these issues are not addressed.

The table below provides a comprehensive summary of the findings made through this review with further analysis and recommendation included within the report.

Finding	Description	Recommendations
1	The forecast assumptions which underpinned the 2012 cost recovery arrangements may not have been appropriate and failed to adequately project beyond the immediate term.	Recommendation 1 – The policy authority should be reviewed in line with the requirements of the updated Australian Government Cost Recovery Guidelines and the Australian Government Charging Framework to ensure the intent remains consistent with the overarching policy. Recommendation 2 – The APVMA should consider refreshing its policy authority to allow for the annual application of indexation. This will ensure that the Authority can amend its pricing annually in line with market factors to ensure revenue and expenditure move consistently across years. Recommendation 3 - The Authority should develop a process by which it can accurately
2	The current policy authority enabling 40% of costs to be recovered through Fee for Service (FFS) impedes APVMAs ability to fully cost recover and drives cross subsidisation	
3	The APVMA does not currently have a process in place to accurately forecast the workload of applications and the modular break up by activity it expects to undertake.	

Finding	Description	Recommendations
4	The policy authority supporting the current cost recovery arrangements does not allow for the annual indexation of charges to take into consideration wage growth and CPI movements.	forecast the number of items/ modules that it expects to process through the year as part of its assessment function. Recommendation 4 - the APVMA should review and update its cost recovery arrangements at the earliest including giving consideration to the appropriateness of the existing policy approval to recover 40% of costs through FFS arrangements.
5	The current cost recovery model is complex, outdated and needs to be updated, the prices set are no longer consistent or reflective of the true costs of undertaking activities.	Recommendation 5 – APVMA should review with current cost recovery model and should make the necessary updates to the model based on the changes implemented to the cost recovery arrangements.
6	Revenue forecasts across the Forward Estimates are optimistic and not representative of actual results and should be revised based on an accurate trend.	Recommendation 6 – APVMA should review its current revenue forecast and amend this to accurately reflect the trend following adjustments for relevant events.
7	The APVMA has not undertaken an effort estimation review and does not have a reliable methodology to align effort against each assessment category including modules and items. The methodology applied to determine the complexity of each assessment module is subjective and has a higher tendency to deliver an in accurate outcome.	Recommendation 7 – APVMA should undertake a review of its current cost base and workforce strategy to determine the cost implications in the short to medium term and either look at reducing costs or increasing pricing to recover justifiable costs. A further option could be for the Authority to investigate outsourcing opportunities as an immediate cost reduction mechanism.
8	There is a risk that the 2017/18 internal expenditure budget allocations for APVMA are aligned to a forecast activity level that may not be achievable due to reduced volumes and decreased revenue.	This report makes no specific recommendation however management should consider the finding and address as appropriate.
9	APVMA should address the gap between revenue and expenditure by updating current cost recovery arrangements to avoid further reductions in the equity reserve balance and its cash position.	Recommendation 8 – APVMA should review its cash flow requirements, and consider what approach or options that are available that will assist in managing its revenue and expenses to minimise the risk of further depleting its cash reserves.
10	Stakeholder’s consistently reported that APVMA’s IT systems were not sufficient to support management. There is extensive manual intervention to extract and manipulate critical financial, HR and Item Activity data. It was also identified that the Authority is reliant on a key individuals to undertake the required manipulation.	This report makes no specific recommendation however management should consider the finding and address as appropriate.

Finding	Description	Recommendations
11	The imbalance between revenue and expenses within the Registrations stream is a result of a shift in costs in undertaking a particular module or item assessment from those derived as part of the 2012 CRIS.	This report makes no specific recommendation however management should consider the finding and address as appropriate.
12	The methodology applied was consistent with past activity based costing reviews and provides a good basis for comparison. Generally though, it should not be relied upon as the basis for adjusting the prices of the modules or items, noting the findings raised through the report.	This report makes no specific recommendation however management should consider the finding and address as appropriate.

2 Background

The Australian Pesticides and Veterinary Medicines Authority (APVMA or Authority) is the Australian Government Authority responsible for regulating agricultural and veterinary (AGVET) chemicals (active constituents) and products containing them in Australia—up to and including the point of retail sale. The sale and use of these chemicals is regulated through a National Registration Scheme (NRS), which is established under Commonwealth, state and territory legislation. The AGVET Code identifies which products and chemicals need to be registered or approved and which ones are exempt. The Code also describes the APVMA’s responsibilities and activities as a regulator—including how the Authority discharges its responsibilities as a regulator.

The current policy authority requires the APVMA to fully recover its costs of operations through a mix of fees, charges and levies imposed on the industry it regulates. These costs are incurred by the Authority undertaking registration assessments, renewing existing product registrations and undertaking compliance, monitoring and enforcement activities to ensure the integrity of the industry. Parties who wish to supply AGVET chemicals must apply to the APVMA to register the products and obtain approval for labels attached to product containers before the products can be supplied, sold, distributed or used in Australia.

When an application for registration is submitted, the APVMA first analyses the data package for completeness of the data, any inconsistencies, and whether the level of detail is sufficient for an adequate risk assessment to be performed. Registration is based on a rigorous and independent evaluation of scientific information related to the safety and efficacy of a product. The APVMA grants registration if the evaluation of a product has shown that it is not likely to be harmful to crops or animals, users, consumers and the environment. The evaluation also has to demonstrate that the product is suitably formulated, and that its label contains adequate instructions for safe and effective use. The APVMA must also assess whether using the product may unduly prejudice trade.

The costs of registrations and approvals are generally recovered through a combination of application fees and the levy, with a greater proportion of the costs recovered through the levy. The costs of assessing applications are collected in two parts: 40 per cent of the assessment costs being charged are to be recovered as an upfront application fee and the balance of revenue required to fund the APVMA’s costs are to be recovered by the levy on the annual value of sales. The policy intent is to ensure that the application fee to assess and register new and innovative products does not act as a disincentive to bringing them into the market, particularly for small businesses, niche products and chemical products that have a low value of sales.

In addition to the registration and approvals function, the APVMA conducts a number of post market compliance activities, which includes GMP assessments, licencing, export certificates and other investigation and enforcement activities. On occasions, the Government may provide funding to the APVMA to fund or subsidise a specific function or reform initiative to lessen the cost impact on industry. Expenses related to undertaking the Government directed activity are generally excluded from the cost recovery arrangements. A summary of the Authority’s pre and post market activities and the appropriate revenue type that funds those arrangements is included in the table below.

Activity	Revenue Type
Pre Market Activities: Registrations and Approvals	
- Item 1-25	Item Fee and Levy
- Modules (for Items which do not have a defined module pathway)	Module Fee and Levy
Post Market Activities	
- Good Manufacturing Practice (GMP) Audit Assessment	Fee
- GMP Licence	Fee
- Certificate of Export	Fee
- Investigation and Enforcement	Fee
Other Agency Activity	
- Implementation of Reform	Funded via Government Appropriation

3 *Current cost recovery arrangements*

Key Findings

- The forecast assumptions which underpinned the 2012 cost recovery arrangements may not have been appropriate and failed to adequately project beyond the immediate term
- The current policy authority enabling 40% of costs to be recovered through Fee for Service (FFS) impedes APVMAs ability to fully cost recover and drives cross subsidisation
- The APVMA does not currently have a process in place to accurately forecast the workload of applications and the modular break up by activity it expects to undertake.
- The policy authority supporting the current cost recovery arrangements does not allow for the annual indexation of charges to take into consideration wage growth and CPI movements.

Analysis of cost allocations has not identified any significant issues with the legitimacy of the nature of the direct and indirect costs attributed to the assessment, registration and compliance programs applied to the AGVET industry as a whole, as the current policy authority requires the Authority to remain fully cost recovered. The review however did identify that the cost recovery arrangements have not been reviewed for a number of years and as a result the costs being attributed to activities may no longer be consistent or representative of the true costs incurred in undertaking that activity.

The current policy authority and the supporting cost recovery arrangements allow the Authority to recover 40% of the cost of the Registration and Approval function via the application fees, with the remainder to be funded via the tiered levy on sales. Despite the changes proposed in the 2012 CRIS, where stepped increases to the application fees were implemented progressively over the two years following (last price update took effect 1 Jan 2015), it is apparent that these changes to prices did not result in a sustained 40% cost recovery from fee for service activities as projected. This is likely due to the following main factors:

- The baseline assumptions is the 2012 CRIS did not consider movements in the expense base beyond the final year of the stepped price changes and assumed the product mix would remain unchanged. This assumption did not materialise because the volume of activity decreased with more complex assessments coming forward requiring a greater proportion of costs to be recovered through the levy charge, which could not fully be recovered through the levy.
- The application mix and the number of items/ modules undertaken as part of the assessments each financial year contributed to the financial losses because effort against these assessment types was not appropriately measured and whilst the volume of activity reduced, the expense base did not.

As part of the 2012 CRIS, the APVMA updated its fee structure, with recommendations concerning changes to the application fees and levy charges, these were then progressively phased in. The structure of application items and modules were left unchanged and remain current to date. From a resource management perspective this was a significant outcome for two primary reasons:

- The Authority currently offers 31 different application items, with each item being comprised of a matrix of different evaluation modules. For the Authority to effectively manage its workforce and expense base, and react to any fluctuations in application numbers, the Authority needs to be able to accurately forecast the volume of each application type it is likely to receive in the coming financial year. With 12 of the 31 item types not having a set evaluation pathway (“modular pathways”), forecasting the number and type of modules to be undertaken can prove difficult as has been evident in the 2012 CRIS which assumed that there would be no change to applications

numbers or mix of applications items as part of recalculating the fees to be charged.

- With no means to reliably forecast the makeup of application items, and by extending the evaluation modules required across the forecast period, the Authority has no reliable means by which it could monitor and adjust its staffing profile, and ensure it retains adequate skillsets required to process certain evaluation modules.

Further as part of the 2012 CRIS, following stakeholder feedback, it was decided that automatic indexation would not be applied to the fees at that time, and would be discussed as part of the First Principles Review (the review ultimately recommended no change from this position). Under current arrangements indexation is not being applied which is contributing further to the variance between income and expenditure

These factors arising from the APVMAs inability to effectively forecast activity, measure effort, project costs and to maintain a current operational cost model with current and valid assumptions have contributed towards the Authority incurring operational losses over the last three financial years which are presented in the table below

	2014-15 \$m	2015-16 \$m	2016-17 \$m
Application and Permit fees	5.9	5.7	5.7
Levies	16.3	16.7	17.3
Annual fees (renewal fees)	4.7	5.0	5.9
Other	1.6	2.1	1.8
<i>Total Revenue</i>	<i>28.4</i>	<i>29.5</i>	<i>30.7</i>
<i>Total Expenditure</i>	<i>33.1</i>	<i>33.8</i>	<i>33.4</i>
<i>Operating Result*</i>	<i>- 4.7</i>	<i>- 4.3</i>	<i>- 2.7</i>

*Operating result attributable to cost recoverable functions

Recommendation 1– The policy authority should be reviewed in line with the requirements of the updated Australian Government Cost Recovery Guidelines and the Australian Government Charging Framework to ensure the intent remains consistent with the overarching policy.

Recommendation 2– The APVMA should consider refreshing its policy authority to allow for the annual application of indexation. This will ensure that the Authority can amend its pricing annually in line with market factors to ensure revenue and expenditure move consistently across years

Recommendation 3 - The Authority should develop a process by which it can accurately forecast the number of items/ modules that it expects to process through the year as part of its assessment function.

Recommendation 4 - the APVMA should review and update its cost recovery arrangements at the earliest including giving consideration to the appropriateness of the existing policy approval to recover 40% of costs through FFS arrangements.

4 *Appropriateness of the cost recovery model and pricing arrangements*

Key Findings

- The current cost recovery model is complex, outdated and needs to be updated, the prices set are no longer consistent or reflective of the true costs of undertaking activities.
- Revenue forecasts across the Forward Estimates are optimistic and not representative of actual results and should be revised based on an accurate trend.
- The APVMA has not undertaken an effort estimation review and does not have a reliable methodology to align effort against each assessment category including modules and items. The methodology applied to determine the complexity of each assessment module is subjective and has a higher tendency to deliver an in accurate outcome.

This review has identified 31 active registration items (some items have been introduced or removed over time) across seven key groups which are represented below:

- Application for approval of active constituent contained in a chemical product, registration of the chemical product and approval of the product label
- Application for registration of a chemical product containing an approved active constituent and approval of the product label
- Application to vary a registration or label approval
- Application for approval of an active constituent
- Application for variation to an approved active constituent
- Application for a permit
- Other applications.

A number of these registration items have a modular pricing arrangement with the work involved in the registration process varying depending on the type of application, which can only be determined after the preliminary assessment has been undertaken. As a result the APVMA schedule of fees also includes costs for 12 different modules of work, with each module type then having up to 4 sub tiers, totalling 39 individual modules. The 12 types of modules vary across the following:

- 1. Preliminary Assessment
- 2. Chemistry
- 3. Toxicology
- 4. Poison
- 5. Residues
- 6. OH&S
- 7. Environment
- 8. Efficacy and target animal safety
- 9. Non-food trade

- 10. Special data
- 11. Finalisation
- 12. Data protection

From a cost modelling perspective activity against each of the areas must be captured to determine the true costs of that specific activity, further the combination of modules undertaken against each assessment must also be identified to derive appropriate pricing arrangements. Due to the level of complexity the outcomes of this effort estimation process can currently be very subjective and as a result provide an inaccurate outcome.

The distinction between modules and categories of registration become especially important in relation to some sections, where the work is classified based on the module being completed rather than the Item of registration being applied for. Their level of effort is essentially unchanged, for example, when completing a module 5.1 residues analysis for an Item 1 registration or an Item 3 registration.

Whilst the APVMA has historically outsourced a number of modules to other Departments or private entities, in 2015/16 a decision was taken to undertake a number of these less complex module assessments internally and reduce outsourcing which has added to the complexity. Due to these factors it is essential that the cost recovery model is reviewed and updated on an ongoing basis especially when there is a significant shift in activity. The review has identified that this has not occurred over a number of years and as a result the cost recovery model is outdated resulting in inconsistent pricing arrangements. Some of the more complex assessments are still outsourced to experienced providers. Based on the information reviewed PwC has been unable to determine the tangible benefits of this insourcing activity.

Recommendation 5 – APVMA should review with current cost recovery model and should make the necessary updates to the model based on the changes implemented to the cost recovery arrangements.

4.1 Industry contributions under current pricing arrangements

APVMA revenue can be attributed across a mixture of industry contributions including Levies, renewal fees, product applications, permits and other fees including goods manufacturing practice. A summary of the industry contribution items across the last two reported Financial Years and the latest forecast for 2016/17 by category are provided in the table below.

	2014-15	2015-16	2016-17
	\$m	\$m	\$m
Levies	16.3	16.7	17.3
Annual fees (renewal fees)	4.7	5.0	5.9
Product application fees	5.6	5.3	5.5
Good manufacturing practice fees	1.0	1.2	1.2
Permits, actives and other fees	0.9	1.3	0.9
<i>Total industry contributions</i>	<i>28.4</i>	<i>29.5</i>	<i>30.7</i>

*2014-15 and 2015-16 results as per APVMA Annual report

The total contributions received have grown marginally across the reporting period, with the majority of the increase resulting from increased annual fees (either via annual renewals charged at \$430, or a 5 yearly renewal charged at \$2,150) with the remainder predominately linked to increased receipts via the levy charged on reported sales. The growth in annual fee revenue would support a view that the

number of new products being brought to market are declining (via decreased applications), with existing products remaining on market (increased annual renewals).

Further the application and permit fees in 2016-17 are projected to make up only 21% of the Authority's overall revenue and that the revenue received via these fees have remained relatively constant in absolute terms, despite consistently falling application numbers each year. This is predominately attributable to the stepped increase in application fees across 2013- 2015 to restore the proportion of costs recovered through a fee for service arrangement. Industry contributions through the various fees and charges have been at the aggregate level relatively consistent since 2010/11, and even applying simple trend forecast, gives the Authority a reasonable basis from which it can forward project its likely future year revenue forecast, however this is not reflected in the current forecasts represented in the Portfolio Budget Statements which demonstrate sustained growth in revenue over the Forward Estimates.

2017/18 PBS	2017-18 \$m	2018-19 \$m	2019-20 \$m	2020-21 \$m
Receipts (Amounts Payable to APVMA)	33.2	33.8	34.3	35.2

Prolonged delays to application processing may overtime, undermine Industry's confidence in the Authority and result in further reduced applications, in favour of the simple renewal of already approved products. If realised, with all other things remaining unchanged, this has the potential to impact the APVMAs earnings, which may however be offset by continued growth in renewal fees. As such, forward projections for this revenue source based on the past 3 year trend are defensible and may be likely to slightly increase in net terms via increases to CPI, as smaller retailers sales totals are pushed into the higher sale tiers whose thresholds are not automatically indexed.

Recommendation 6– APVMA should review its current revenue forecast and amend this to accurately reflect the trend following adjustments for relevant events.

4.2 Review of cost base

Total APVMA expenses (normalised for funding received from Government to undertake regulatory reform or other change activities) has exceeded revenue receipts since at least 2014-15. A breakdown of the expenses by category is provided in table 6 below, and depicts the major contributors by category. The costs are inclusive of all activities which APVMA undertakes including compliance, licencing, enforcement and other administrative activities.

Category	2014/15		2015/16		2016/17	
	\$m	% of Total Expenses	\$m	% of Total Expenses	\$m	% of Total Expenses
Salary/Super/AL & LSL provisions	\$ 21.7	65.5%	\$ 22.8	67.4%	\$ 24.1	72.2%
Salaries and Superannuation	\$ 19.9	60.1%	\$ 21.2	62.6%	\$ 22.5	67.2%
Casual Staff (Via Agencies)	\$ 1.8	5.5%	\$ 0.8	2.5%	\$ 1.1	3.4%
AL & LSL provisions	-\$ 0.2	-0.5%	\$ 0.5	1.5%	\$ 0.3	1.0%
Recruitment	\$ 0.1	0.2%	\$ 0.2	0.5%	\$ 0.2	0.5%
Other Employee Expenses	\$ 0.1	0.3%	\$ 0.1	0.2%	\$ 0.0	0.1%
Training & Development	\$ 0.3	1.0%	\$ 0.2	0.5%	\$ 0.2	0.5%
Consulting Fees - Other	\$ 0.7	2.1%	\$ 0.6	1.7%	\$ 0.6	1.9%
Scientific Assessment Services	\$ 5.1	15.3%	\$ 5.1	15.0%	\$ 2.5	7.4%
Travel & Accomodation	\$ 0.2	0.6%	\$ 0.2	0.6%	\$ 0.1	0.4%
IT Software & Licence Expenses	\$ 0.5	1.6%	\$ 0.5	1.4%	\$ 0.6	1.6%
Communication Expenses	\$ 0.3	0.9%	\$ 0.4	1.3%	\$ 0.4	1.3%
Rent, Outgoings & Building Maint.	\$ 1.5	4.6%	\$ 1.5	4.3%	\$ 1.6	4.8%
Audit Fees	\$ 0.2	0.7%	\$ 0.1	0.4%	\$ 0.1	0.2%
Insurance	\$ 0.1	0.4%	\$ 0.2	0.7%	\$ 0.3	1.0%
Bank and Interest fees	\$ 0.1	0.3%	\$ 0.1	0.2%	\$ 0.1	0.2%
Legal Expenses	\$ 0.4	1.1%	\$ 0.1	0.4%	\$ 0.5	1.4%
Other Supplier Expenses	\$ 0.7	2.2%	\$ 0.5	1.6%	\$ 0.6	1.8%
Depreciation on Assets	\$ 1.2	3.7%	\$ 1.5	4.5%	\$ 1.7	5.1%
Total Expense	\$ 33.1	100%	\$ 33.8	100%	\$ 33.4	100%

The cost base of the Authority has been relatively stable over time, there are two key categories that continue to account for approximately 80% of the Authority's total costs: Employee costs (predominately comprising of Salary and Superannuation expenses) and Scientific Assessment Services (contractor costs). Analysis undertaken in the review indicates that while the volumes of activities have decreased the increase in the level of complexity of activities being undertaken have resulted in the costs remaining relatively stable. In the absence of an in depth review of effort against each activity, this assumption is difficult to test, however we have used previous estimates and recent management estimates to qualify this assumption.

Further analysis on the material expenditure categories is presented below

Employee Costs

These costs have continued to grow year on year, and are driven by two main factors:

- Total FTE numbers have increased by approximately 10% over the reported period (165 FTE at the end of 2014/15 to 189 FTE in 2016/17) increasing costs. This growth has been almost entirely constrained within the Registration Management and Evaluation and Scientific Assessment and Chemical Review teams. This increase is considered reasonable noting the Authority's decision to insource Scientific Assessment Reviews.
- Staff progressing through the pay band, being placed in long term acting arrangements and/ or being promoted have contributed to a further increase. APVMAs 2017- 2020 Enterprise Agreement which took effect on 26 April 2017, and includes two further pay increases in April 2018 and April 2019 of 2% for all classifications will likely continue to drive these expenses higher. This is particularly important, as whilst the 2012 CRIS did account for growth in employee costs out to 2014/15, there was no consideration given to the foreseeable increases in these costs through subsequent Employee Agreements.

Scientific Assessment Services (SAS)

SAS services are outsourced activities previously undertaken for APVMA through a supplier arrangement by other Government departments as well as some private providers. SAS costs have historically averaged approximately \$5m per year (this was the basis of estimate in the 2012 CRIS). In 2015/16 the APVMA brought a number of these reviews in house, using APVMA staff, to ensure ongoing capability. The APVMA also made assumptions that this insourcing would reduce costs.

The assumptions the insourcing would reduce costs involved:

- Reduced regulatory burden on the AGVET industry would mean less complex assessments are required going forward.
- Overtime, improved staff qualifications to undertake analysis in house would further reduce reliance on outsourcing to other providers reducing costs in the future.
- Improved access to external scientific reviews (including from other jurisdictions) would reduce the demand for the volume of reviews required and result in reduced costs for the Authority.

In 2016/17 costs directly attributable to SAS costs have roughly halved from previous years, though this is offset at least partly by the increase in FTE and employee salary costs as discussed above indicating that the benefits from reduced costs may have been over estimated in the short term. From a cost management perspective, this decision is significant as the Authority has effectively transferred an inherently variable cost (contractor costs) to a fixed cost (FTE). In instances where staff are underutilised (i.e. no modules requiring such assessments) their costs are not being recovered and it is difficult for the Authority to remove or shift the expense in accordance with shifting demand. Whilst the need to maintain capability underpinned the decision to in-source these reviews, with no means to reliably forecast the demand for those modules which would require such assessments, the overall savings that were assumed to be derived may be negligible or overstated. There is a high likelihood that initially at least, the costs per review may be higher than previously.

Whilst a significant portion of the APVMAs costs can be attributed to registration activities there are a number of compliance and administrative activities also undertaken by the Authority. The table below depicts a high level breakdown between the registration and compliance and other elements of the business, as drawn from the previous cost recovery review conducted in 2015 (on 2014/15 financials) and work undertaken through this review (2016/17 financials). An average of the two results has been

used to provide an indicative split for 2015/16 financials by section.

Activity Based Costing by Section	2014-15	2015-16	2016-17
Section	\$m	\$m	\$m
Registration Sections	25.5	26.8	27.1
Compliance and other Sections (MQL, Chemical Review, Compliance)	7.6	7.1	6.3
Percentage of Costs allocated to Registration Activities	77%	79%	81%
40% of Registration Section Cost	10.2	10.7	10.9

The figures presented above show that at the aggregated level, the percentage of total Authority costs associated with the registration function has increased year on year. This is partially offset the costs associated with Compliance and other administrative activities trending downwards. The registration function represented 81% of total Authority costs in 2016/17.

Analysis of the drivers underpinning the increase which were validated through the effort survey undertaken as part of this review indicated that

- The surveys indicated that an increased proportion of management level staff time was being spent on non- registration related activities. In a period of heightened organisational change this can be expected, though as the entirety of the costs of those staff are allocated to the application items and modules, any increase in effort associated with non-registration activities would still have an increasing cost impact on to each application item and module undertaken by that section, though without the associated effort that may allow for more applications to be processed.
- The surveys also indicated that an increased proportion of time spent on general application processing was attributable to staff, which external stakeholders speculate is attributable to staff turnover and loss of technical knowledge, however as the APVMA does not have a current time capture system in place that would allow for staff productivity to be monitored and measured we could not confirm at this time. A productivity and efficiency review was not undertaken as part of this review however it may be possible that due to the vast number of changes and loss of corporate knowledge previously established KPIs may have been missed resulting in additional effort and costs.
- The decision to outsource lower quantities of SAS reviews in favour of conducting more of these internally may not at this stage have returned benefits and were possible overstated. This is likely due to two main reasons:
 - o It is not unreasonable, initially at least, to expect the cost of undertaking these reviews are higher than had they been outsourced as staff take time to develop their skillsets. Assuming a relatively stable staffing cohort, over time the reviews will become more efficient and reduce costs; and
 - o modules which would normally require a specific SAS review are generally tied to those application items which have inherently complex pathways, and require modules to be undertaken which are not necessarily common. Whilst it must be emphasised that this was not specifically raised, there is certainly a risk that the Authority maybe incurring heightened costs by maintaining a pool of resources to undertake reviews which are not common. The siloed nature of the resources could potentially be addressed by having staff capable of moving between disciplines and this may be one of the more obvious areas where the Authority is able to adjust its cost base to align with demand (and may have been the reason the SAS reviews were outsourced initially).

Recommendation 7– APVMA should undertake a review of its current cost base and workforce strategy to determine the cost implications in the short to medium term and either look at reducing costs or increasing pricing to recover justifiable costs. A further option could be for the Authority to investigate outsourcing opportunities as an immediate cost reduction mechanism.

5 Overview of current financial operations

Key Findings

- There is a risk that the 2017/18 internal expenditure budget allocations for APVMA are aligned to a forecast activity level that may not be achievable due to reduced volumes and decreased revenue.
- APVMA should address the gap between revenue and expenditure by updating current cost recovery arrangements to avoid further reductions in the equity reserve balance and its cash position

The APVMA has operated at a financial loss for the last three financial years, with the most recent loss in 2016/17 being approximately \$2.401m (normalised for Government funding received and the costs associated with those activities). Whilst the proportion of total revenue earned between the different fees and charges has shifted year to year, overall revenue has remained constant, and this would ordinarily allow the APVMA to take the required actions to reduce its expenses appropriately. The Authority's inability to avoid concurrent losses is a cause for concern as it would result in financial sustainability issues in the short term with no improvements projected in the longer term.

Whilst it may be argued that the financial losses are resulting from a mismatch between revenue and expenditure and could be addressed by readjusting prices, to determine longer term sustainability the APVMA should review its cost base, analyse its activity forecast and undertake a detailed time and motion study to help restate a baseline position.

What is most certainly apparent through the analysis undertaken, is that some of the assumptions applied in the modelling as part of the 2012 CRIS although accurate at that point in time did not materialise and have not been revised since then due to a number of contributing factors. Some of the key factors that support this assumption include

- The model assumed that the total number of product applications would remain relatively stable over a period of time and that there would be no change in the application makeup. Further there was no recognition that there would be a change in the makeup (for instance an increase in the number of Item 2 applications, which have a modular pathway) or how this change could have a material impact on the total number of modules undertaken across a given period. The implications of this assumption has impacted both the revenue and expenditure.
- The derived cost per item and module was based on a total cost allocation across the expected volume to be processed each year. There was no consideration as to how much effort (measured in hours) a particular module would take to complete, nor the impact a change in the product mix would have on related modules undertaken by staff within the same section. I.e. an increase to a particular modules volume at the expense of another may not necessarily have an equally offsetting impact on the derived cost.
- Growth in the operating expenditure allocation was tied entirely to a weighted average of the forecast Wage Price Index and Consumer Price Index (3.4% was the weighted average applied to each year out to 2014/15). The model did not assume these changes to be enduring, and in effect ensured that as the prices remained constant beyond 2014/15, expenses would overtime become misaligned.
- The CRIS included forecast operating outcomes out to 2014/15, which were based on actual outcomes for 2011/12, and introduced stepped increases to the fees over a number of years. Phase 2 and 3 (an increase of all fees to 35 and then 40 percent of total costs) were to be implemented on 1 July 2014 and 1 January 2015 respectively. However the model was not updated with revised assumptions which were more closely aligned to actual results and as such the nexus was lost.

The above misalignment between the assumptions made and the resulting outcome is evident in the table below which demonstrates the importance of ongoing reviews and updates that are required to cost recovery models, their base assumptions, forecasts and inputs.

The contents of the tables emphasise the important of this by detailing items finalised from 2014-15 through to 2016-17 and total associated modules processed to achieve that finalisation. It is clear, that there is not a distinct 1:1 relationship, evidenced by a 33% drop in items finalised, but only a 22% drop in modules undertaken.

Item	Items Finalised				Modules Processed			
	2014-15	2015-16	2016-17	% Change	2014-15	2015-16	2016-17	% Change
ITEM 01	9	10	5	-44%	81	90	63	-22%
ITEM 02	47	19	33	-30%	216	141	224	4%
ITEM 03	2	-	1	-50%	18	-	9	-50%
ITEM 04	2	-	-	-100%	18	-	-	-100%
ITEM 05	56	26	20	-64%	224	106	90	-60%
ITEM 06	96	6	21	-78%	286	25	81	-72%
ITEM 07	397	245	153	-61%	794	260	163	-79%
ITEM 08	205	158	137	-33%	410	170	147	-64%
ITEM 09	6	1	2	-67%	12	3	2	-83%
ITEM 10	309	161	178	-42%	1,147	677	834	-27%
ITEM 10A	5	71	30	500%	5	72	33	560%
ITEM 11	7	3	-	-100%	42	17	-	-100%
ITEM 12	581	281	198	-66%	581	326	218	-62%
ITEM 13	62	17	8	-87%	62	21	10	-84%
ITEM 13A	174	300	210	21%	174	305	220	26%
ITEM 14	737	295	240	-67%	1,386	1,016	776	-44%
ITEM 15	6	2	4	-33%	12	10	20	67%
ITEM 16	2	7	2	0%	4	34	9	125%
ITEM 17	90	151	538	498%	90	459	1,639	1721%
ITEM 18	11	35	93	745%	11	45	95	764%
ITEM 19	31	27	11	-65%	31	31	11	-65%
ITEM 20	242	233	174	-28%	250	239	183	-27%
ITEM 21	191	191	107	-44%	262	413	246	-6%
ITEM 22	46	27	53	15%	66	37	105	59%
ITEM 23	130	74	71	-45%	164	123	119	-27%
ITEM 24	11	-	-	-100%	39	-	-	-100%
ITEM 25	-	-	-	-	-	-	-	-
ITEM 27	-	-	7	-	-	-	68	-
Total	3,455	2,340	2,296		6,385	4,620	5,365	

The table above also demonstrates the volume, type and mix of items and modules may vary significantly across the year and cannot be used as a representation of effort incurred in that year. In addition to the number of applications steadily declining, the APVMA's most recent (end March 2017 quarter) published performance statistics are reporting longer timeframes and lower number of applications being finalised. As discussed earlier, prolonged delays to application processing may overtime, undermine Industry's confidence in the Authority and result in further reduced applications, in favour of the simple renewal of already approved products. If realised, with all other things remaining unchanged, this has the potential to undermine the solvency of the Authority in the short to medium term.

5.1 Management of the APVMAs Equity Reserve

The APVMA operates with a target equity reserve equal to approximately 3 months of operating expenses, as derived at the time of the last CRIS, on average to be equal to \$7m. This amount was to be in addition to the working capital requirements of the Authority to meet staff payment liabilities and vendor payments. Since the 2012 CRIS, the equity balance has been relatively variable, owing to a number of equity injections (such as the Better Practice Reforms), with some of these funds later repaid, and the re-classification of Industry receipts to be recognised as income earned at the time of cash being received. From a cash perspective, the Authority's equity balances since 2010/11 is included in the table below.

APVMA Equity Balance	2010-11*	2011-12	2012-13	2013-14	2014-15**	2015-16	2016-17***
	\$m	\$m	\$m	\$m	\$m	\$m	\$m
Contributed equity	-	0.4	0.4	0.4	5.5	-	Not Currently Available
Reserves	0.1	0.1	1.1	1.1	1.1	10.5	
Retained surplus	7.3	11.9	11.0	7.3	3.8	3.3	
Other comprehensive income	-	-	-	-	-	0.1	
Total equity	7.4	12.4	12.5	8.8	10.5	7.3	

* Additional appropriations in 2010-11 and 2011-12 for Better Regulation reforms totalling \$8.750m, \$2m was returned in 2013-14

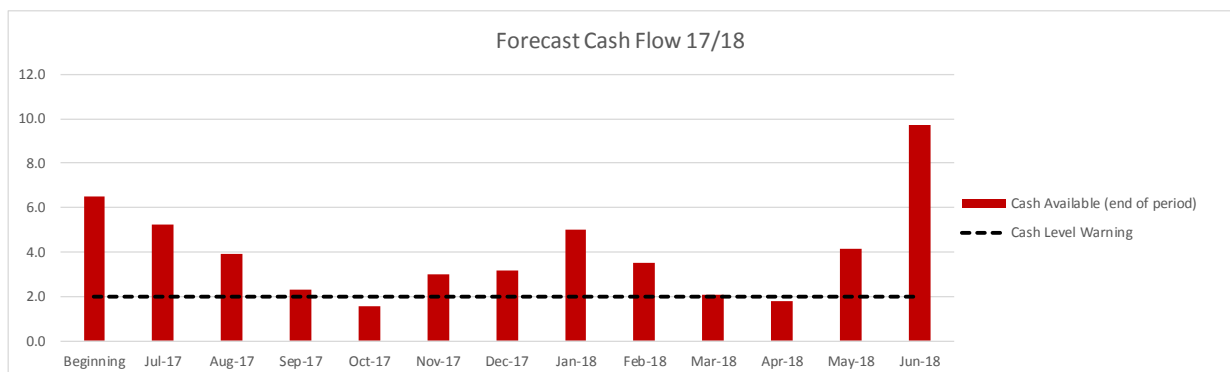
** Increase a result of recording fees and charges as equity injection \$5.155m (recognition as income earned and not unearned revenue)

*** 2016-17 balance excludes equity provided for reform and relocation (\$2.139m)

As above, the Authority operates under a plan to retain a cash reserve of approximately \$7m to cover periods of variations between revenue and expenses as a result of volatility in activity volumes. Whilst the Authority has generally held amounts close to this amount in its equity reserves at the end of each reporting year, the trend (normalised for equity injections) has been for the balance to progressively decrease.

In the immediate terms, of concern is the cash flow of the Authority throughout the financial year, which is depicted in table and graph below.

	Beginning	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Total
Forecast Cash Receipts		1.4	1.1	0.9	1.8	4.0	2.6	4.4	0.9	1.1	2.1	4.9	7.9	33.2
Available Cash	6.5	7.9	6.4	4.8	4.1	5.5	5.6	7.6	5.9	4.6	4.2	6.7	12.1	39.7
Forecast Cash Paid	0.0	2.6	2.5	2.5	2.6	2.5	2.5	2.5	2.4	2.5	2.4	2.5	2.4	30.0
Cash Available (end of)	6.5	5.3	3.9	2.3	1.6	3.0	3.1	5.0	3.5	2.0	1.8	4.2	9.7	9.7



Cash level warning threshold represents the cash required to make 2 salary payments to all staff (exc contractors) each month based on the 17/18 internal budget

The two key issues identified through this high level analysis indicates that

- The revenue projections are premised on total Industry receipts of \$33.237m, which may be considered unachievable and could be presenting a false sense of security from which the Authority can fund its expenses.
- Through relatively stable cash outflows (salaries and superannuation constitute on average \$1.8m per period), the cash balance from the start of the year (\$6.479m) is steadily reduced through these regular payments.

Recommendation 8 – APVMA should review its cash flow requirements, and consider what approach or options that are available that will assist in managing its revenue and expenses to minimise the risk of further depleting its cash reserves.

6 *Cost Model Update and Fee Analysis*

Key Findings

- Stakeholder's consistently reported that APVMA's IT systems were not sufficient to support management. There is extensive manual intervention to extract and manipulate critical financial, HR and Item Activity data. It was also identified that the Authority is reliant on a key individuals to undertake the required manipulation.
- The imbalance between revenue and expenses within the Registrations stream is a result of a shift in costs in undertaking a particular module or item assessment from those derived as part of the 2012 CRIS.
- The methodology applied was consistent with past activity based costing reviews and provides a good basis for comparison. Generally though, it should not be relied upon as the basis for adjusting the prices of the modules or items, noting the findings raised through the report.

The 2017 cost modelling review was conducted using the same attribution model as that used in previous updates, with adjustments made as required to account for changes in APVMAs structure or operations. As with past reviews, the consultation phase involved updating the time effort surveys that would be used to allocate staff effort against different activities where necessary. Team leaders were asked to determine what activities their section undertook, what percentages of time their staff spend undertaking these activities, how these activities correlate to the modules of work completed in each section, and finally to weight the complexity involved in undertaking these modules against each other.

Owing to the differing information provided by each section, as outlined above, each part of the model relating to a particular section was bespoke to meet the requirements of, and to take account of the different characteristics of, each section. The cost model was designed to capture information for each section that undertook work that related to modules and items– i.e. those sections that directly contributed towards the registration and approvals function for which expenses are partly recovered through the application fee. The remaining areas were not modelled as their expenses, taken in aggregate inclusive of overheads, were not related to assessments undertaken through the modules and items.

The costs incurred by the relevant sections of APVMA listed below were included within the cost modelling:

- Registration
- Applications Management and Enquiries
- Chemistry
- Residues
- Manufacturing Quality & Licencing (MQ&L)
- Chemical Review
- Compliance
- Permits
- Efficacy
- Environment
- Health

The outputs of each of these sections were brought together and aggregated in the summary model. The financial data upon which the cost of registration categories and modules was based was the 2016/17 financial year data to the end of June 17 for the whole of APVMA, and was exclusive of any Government funding specifically appropriated to the Authority (to fund reform activities for example). This total amount was broken down by section. The costs for sections that did not undertake activities relating to cost recovery, but provided the necessary support to these activities, were combined and formed the basis of the Corporate Overheads.

The nature of the work undertaken as Scientific Assessment Services (SAS) is traceable to a number of different modules. The amount of expenditure relating to the use of SAS was able to be separately identified from the Authority's FMIS. Whilst the payment detail within the financial data did not allow for a direct mapping of the outsourced assessment to a specific module, the Authority records such details in a separate spreadsheet. This allowed for the direct mapping of SAS expenses to the section responsible for that module. Where expenses could not be apportioned directly, this was added to the Overhead allocation and allocated on that basis.

Full-time equivalent (FTE) data was used to attribute the total cost to each of the sections. Median salaries were weighted to take into account different teams being comprised of different levels of staff.

Non-service delivery activity costs needed to be attributed as part of the model to provide a full cost of registration activities. As such, all non-service delivery costs were aggregated and allocated to the each section. Corporate overhead costs capture the costs associated with the Public Affairs, Principal Scientists, Legal, the Executive, Information Technology, Information Services, Human Resources, Finance and Corporate.

An assumption was made that all direct areas would draw equally upon corporate overheads and the most appropriate driver to apply would be FTE.

While the key activities within section MQ&L, Compliance and Chemical Review were identified during the consultation phase, as these activities do not directly correlate with the application process, the associated costs (including the relevant component of corporate overheads) have not been directed to any registration item or modular category. These costs however were still captured and presented as distinct outputs in the summary model to allow for analysis as required, and to ensure that the model attributes all costs of the APVMA.

The overall cost of each item, and the fee charged is determined and driven primarily by the modules that encapsulate each respective Item type. As each registration item is composed of different modules, by accurately costing each module, and then calculating costs of each registration category as a sum of all relevant modules an accurate cost base for each item can be derived. This approach also eliminates any instances where the cost associated with a registration item is not equal to the sum of all the individual modules that compose it.

Appendix A – Scope and Approach of Review

Scope of work performed

In accordance with the agreed terms of reference for the review, PwC reviewed the cost recovery arrangements currently supporting the operations of the APVMA to determine if they were adequate, compliant with the overarching Australian Government Cost Recovery Guidelines and were supporting the Authority in achieving its policy objectives of remaining fully cost recovered.

In accordance with these terms, the overarching scope of the review was to validate the cost recovery model and all costs (and therefore prices) to be applied for the assessment and registration of AGVET medicines and products. In particular, the review was tasked to consider:

1. the cost base of APVMA operations
2. if the costs being recovered by the APVMA are legitimately costs for industry (and not costs of government)
3. if the current cost recovery arrangements were fully recovering the costs incurred by the APVMA
4. the appropriateness of the existing cost recovery arrangements, cost model and price settings
5. how all APVMA costs are currently being attributed to the AGVET industry
6. whether the existing arrangement is defensible, equitable and consistent with Australian Government Cost Recovery Guidelines.

Where the review identified areas of potential concern, we have proposed recommendations. While intrinsically linked to the effectiveness of the cost recovery arrangements, this report does not comment on implementation activities and current operational effectiveness of the APVMA.

Review Approach

Historically the APVMA generally recovered less through the cost recovery arrangements than the actual costs incurred to undertake its operations, this was confirmed through a previous cost recovery review undertaken by PwC.

Further in 2014 the Department of Agriculture and Water Resources (DAWR) also undertook a First Principles review of APVMA's cost recovery arrangements to make recommendations and identify options to strengthen the financial sustainability, transparency and accountability of those arrangements, however none of those recommendations or options have been actioned to date.

Our approach to the review has taken the above into consideration and focussed on analysing the current financial operations of the APVMA and assessing whether there are any sustainability issues that the Authority should consider and address in the immediate future.