Australian Pesticides & Veterinary Medicines Authority

Report of Operations

Australian Pesticides & Veterinary Medicines Authority

Year in Review

Corporate profile

Vision

To be recognised nationally and internationally as a best-practice regulator of pesticides and veterinary medicines that has the respect and confidence of governments, the community, the rural sector, chemical users and the chemicals industry.

Mission

To protect the health and safety of people and animals, the environment and trade and support Australian agriculture, through science-based, effective and efficient regulation of pesticides and veterinary medicines.

Who we are

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent Australian Government statutory authority responsible for the registration of pesticides and veterinary medicines prior to sale and their regulation up to and including the point of retail sale.

Responsible Minister

The APVMA is within the portfolio of the Minister for Agriculture, Fisheries and Forestry, the Hon Warren Truss MP.

Senator the Hon Judith Troeth, Parliamentary Secretary to the Minister for Agriculture, Fisheries and Forestry, has direct portfolio responsibility for the APVMA. The APVMA Chairperson reports regularly to Senator Troeth on APVMA activities.

What we do

The work of the APVMA protects the health and safety of people, animals, the environment and trade.

The APVMA is responsible for administering and managing the National Registration Scheme. The scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia. The APVMA does this in partnership with the State and Territory governments and with the active involvement of other Australian Government agencies. The APVMA administers and manages the scheme's legislation and is responsible for registration, quality assurance and compliance of pesticides and veterinary medicines up to and including the point of retail sale. All registered products must be shown to work, be safe for people and the environment and not jeopardise Australia's trade with other nations. The

APVMA also manages a number of programs that monitor the ongoing safety and performance of these registered products. The responsibility for the control of use of pesticides and veterinary medicines lies with the individual States and Territories.

Governing legislation

The APVMA operates in accordance with its governing legislation, the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act) and the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code).

The Administration Act sets out the APVMA's role as an independent statutory authority to undertake the Australian Government's responsibilities under the National Registration Scheme. The Agvet Code details operational provisions for approving active constituents, registering chemical products and approving labels.

Stakeholders

In undertaking its role, the APVMA consults with a range of stakeholders including:

- the general community
- the chemicals industry
- the Australian, State and Territory governments
- farmers and farm workers
- other users of agricultural and veterinary chemicals
- other national and international regulators.

Funding arrangements

APVMA activities are funded on a cost recovery basis with operational revenue being collected mainly from registrants of pesticides and veterinary medicines. Fees are paid to apply for, and annually renew, product registrations. Levies are paid annually according to the level of disposals of registered products. In 2003–04 industry contributions were 95 per cent of total revenue (2002–03: 95 per cent).

As an agency operating on full cost recovery, business efficiency and customer service are key priorities for the APVMA.

Report by the Chairperson and Chief Executive Officer

Dr Kevin Sheridan AO
Chairperson

Dr Joe Smith
Chief Executive Officer

Significant change and reform best characterised the past year for the APVMA. That change brought with it a number of challenges but also great promise for the future. Part of the change that the organisation experienced concerned the make-up of the organisation's senior management. Dr Joe Smith was appointed as the new CEO of the APVMA in November 2003, replacing Dr Alison Turner who had successfully led the APVMA for six years. Dr Turner can be justifiably proud of her work in shaping the APVMA into one of the best regulators of its type in the world.

As well, two new program managers joined the senior management team over the year. Dr Eva Bennet-Jenkins was appointed Manager of the Pesticides Program and Dr Tim Dyke was appointed Manager of the Quality Assurance and Compliance Program. Both new program managers have enviable skills and experience and the great respect of their scientific peers both nationally and internationally.

Many of the other major changes over the year involved the implementation of new initiatives or the enhancement of existing programs. A few key examples include:

- the successful launch of the Adverse Experience Reporting Program for agricultural chemicals that provides a mechanism for the APVMA to receive feedback on the performance of agricultural chemicals and to respond to matters of concern should they arise
- the implementation of a new quality assurance scheme for agricultural active constituents and agricultural chemical products. The scheme will help achieve greater ongoing compliance of agricultural active constituents and products with applicable standards
- leadership of a new program to improve the management of minor use issues in Australia
- reforms to the way export trade risks are managed through major enhancements to the establishment of export intervals and communication of trade risks.

Achievements for 2003–04

There are three strategies that are fundamental to the APVMA Board's leadership of the organisation to achieve continuing successful performance. These are confidence building, operational excellence and informing policy. In reflecting on the achievements of the past year it is useful to consider what we have been able to achieve in the pursuit of each of these strategic themes.

Confidence building

The APVMA has made considerable progress in our efforts to build and maintain the confidence of stakeholders in our expertise as the regulator and in the regulatory system that we manage. This has been achieved not only by the way we operate but also by enhancing the focus we have given to our communication strategy.

We have significantly reformed the way we operate our key committees for interaction with the community, the chemical industry and our regulatory partners, the State and Territory governments. The committees are now focused on addressing strategic issues and delivering real outcomes, rather than simply providing a forum for the exchange of information. We have also improved our interaction with users of pesticides and veterinary medicines, holding a Minor Use forum and with plans for a Users forum next year well progressed.

The APVMA Board approved a communication plan that targets the community, chemical users, the chemical industry and the government sector through a range of initiatives to increase awareness and support for the APVMA. One important initiative in the plan is the 'account manager' concept that is being introduced. This involves the appointment of different APVMA personnel to closely manage relationships with specific stakeholder bodies. The account manager will, in effect, become the stakeholders' key liaison point in the APVMA on issues of interest.

Greatly increased attention has also been given to meeting with individual key stakeholders to foster a solid mutual understanding of important issues and perspectives. As part of this the CEO met with key figures in government (Australian and State agencies), the chemical industry and grower and community organisations. The APVMA Board has also now instituted a practice of inviting key stakeholders to meet with it as part of its regular meetings.

Operational excellence

Over the year the APVMA made impressive progress in reforming many of our key processes. Those reforms are already making a valuable contribution to the calibre of our operations.

Our registration processes, particularly in relation to label approvals, have undergone major change following the introduction of a first tranche of legislative amendments. These changes have been implemented effectively, though not without challenge, and in a way which has optimised efficiencies.

The APVMA compliance program has also been strengthened to include a more focused risk-based approach and increased preparedness to use our full range of compliance powers if and when required.

Efforts to develop our capacity to conduct business electronically have continued. Levy payments are now able to be made electronically and we are trialling the electronic submission of product registration data. Submissions as part of the Adverse Experience Reporting Program for veterinary chemicals (AERP *Vet*) can now be made electronically.

The quality of the science in the APVMA is vital to its continued effectiveness. The APVMA's Principal Scientists conduct an annual review of registration evaluations as part of our focus on consistency and on good science. A Standard on Good Regulatory Science Practice is also being developed to articulate a clear basis for regulatory science quality assurance.

On the broader corporate front, APVMA management and staff are to be complimented on the development of a new Certified Agreement to guide working conditions over the next three years. It is a responsible and appropriate agreement that provides a sound framework for staff to achieve their full potential while serving the goals of the organisation well.

Informing policy

While the APVMA is essentially a regulatory agency and not directly involved in policy development, we do have the capacity and an obligation to contribute to the policy formation process through the provision of advice drawn from our wide knowledge and experience.

Policy development relating to the National Registration Scheme for agricultural and vertinary chemicals is the responsibility of the Australian, State and Territory governments as represented by the Primary Industries Ministerial Council and Primary Industries Standing Committee.

The APVMA directly contributed to the work of the Product Safety and Integrity Committee of the Primary Industries Standing Committee in the development of national operating principles and performance measures for agricultural and veterinary chemicals. It also contributed to the committee's policy reform work on user awareness and training.

We also had extensive input to the legislative program undertaken by the Australian Government Department of Agriculture, Fisheries and Forestry concerning data protection and a range of other amendments to the Agvet Code.

The APVMA was active in engaging with a number of international organisations, to ensure that the quality and efficiency of regulation in Australia remains international best practice and that we influence important international standards. We played a leading role and had input to the policy development activity of the Organisation for Economic Cooperation and Development (OECD) Working Group on Pesticides, the

International Cooperation for Harmonisation of Technical Requirements for Registration of Veterinary Medical Products (VICH) and the Codex Alimentarius Commission. In November 2003 the APVMA had the honour of co-hosting (with the Australian Government Department of Agriculture, Fisheries and Forestry) meetings of the OECD's Registration Steering Group and Risk Reduction Steering Group. These groups are important bodies within the OECD framework in pursuing harmonisation of pesticide regulation, information exchange and the promotion of pesticide risk reduction. The fact that the APVMA was given the opportunity to host the meetings was a reflection of the high regard that exists for Australia's pesticides regulatory system on the international stage.

A year of challenges

The APVMA can be proud of its achievements over the past year. These achievements were hard won in the face of numerous challenges that this year of change brought with it.

The implementation of the many registration process changes, necessary as a result of the amendments to our legislation, placed great pressure on our capacity to meet timeframes. This presented a major challenge for the organisation but we are pleased to say the APVMA has been able to meet the challenge. This is addressed in detail in the body of the report.

We mentioned earlier that the Adverse Experience Reporting Program for agricultural chemicals and the Quality Assurance Scheme for agricultural active constituents and products were significant initiatives for the APVMA in the year and of fundamental importance to our regulatory role. Their implementation was, however, challenging, particularly in relation to managing the different expectations and impacts of the major reforms for various stakeholders.

One of the greatest challenges we faced in 2003–04 related to financial management. The drought had a major impact on revenue raised through levies on chemical sales, with the revenue collected for the year being less than that for 1999–00. While the APVMA has had a strong focus on cost control and productivity improvement since its inception, there has been a significant increase in workloads in recent years, through increased application numbers, the need to introduce new programs and legislatively driven change.

The future

The year ahead seems certain to be another strong one for the APVMA when we will again experience considerable innovation and reform aimed at further enhancing our world-class National Registration Scheme. The three strategic themes of confidence building, operational excellence and

informing policy will continue to guide the performance of the organisation in meeting the needs of all our stakeholders.

A vital element of our future effectiveness and financial security must be to work with government and stakeholders to resolve the issues involved with the new cost recovery framework so that it can be implemented by 1 July 2005.

We have made outstanding progress over the last few years in strengthening the quality of what we do and the efficiency with which we do it. These gains will be consolidated and extended further in the year to come. We will implement further reforms to our registration processes and a major impact is likely to come from proposed legislative changes to data protection provisions.

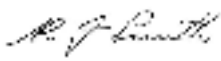
Considerable energy and focus will be directed at ensuring that the Adverse Experience Reporting Program for agricultural chemicals and the Quality Assurance Scheme for agricultural active constituents are operating fully and effectively. We will also be continuing our focus on reform of the minor use framework.

Understanding the concerns and perspectives of our stakeholders and meeting their needs will continue to be of great importance to the APVMA and our continued commitment to the strategy of confidence building demonstrates that. The account manager scheme will be fully operational in 2004–05 and we will strive to consolidate and extend the reforms already begun to our stakeholder liaison forums.

The APVMA has undergone some significant changes through reforms to the way we operate and by implementing new programs. Our achievements have been critically dependent on the outstanding contribution of our staff in all areas of the organisation. We applaud their unceasing dedication, professionalism and effort.

Overall we have managed the challenges of the year successfully and are a better organisation now for it. We have a heightened emphasis on quality and a greater preparedness to confront difficult issues and take strong action if the occasion demands. We have a new Operational Plan, developed for the first time using the Balanced Scorecard Methodology, and are in great shape to take on the challenges of the future.

Dr Kevin Sheridan AO
Chairperson



Dr Joe Smith
Chief Executive Officer

Performance framework

Through the development of a world-class registration scheme for pesticides and veterinary medicines, the APVMA delivers the outcome of protecting the health and safety of people, animals and the environment and supporting Australian agricultural and livestock industries.

The APVMA has developed a performance framework that links its legislative objectives to an outcome-outputs model. This framework involves a detailed planning and reporting process incorporating the Portfolio Budget Statement, Corporate Plan, Annual Operational Plan and Annual Report.

The outcome, outputs and related performance indicators identified in the APVMA component of the Australian Government Department of Agriculture, Fisheries and Forestry Portfolio Budget Statements for 2003–04 reflect the APVMA's Corporate Plan 2003–04 to 2005–06. The Corporate Plan identifies the APVMA's corporate objectives. It presents a single outcome and a key output as outlined in the Portfolio Budget Statement that is supported by two principal goals. This information provides the basic framework for the presentation of the APVMA's performance for 2003–04.

The APVMA's outcome, key output, corporate objectives, strategies and performance indicators are illustrated in Figure 1.

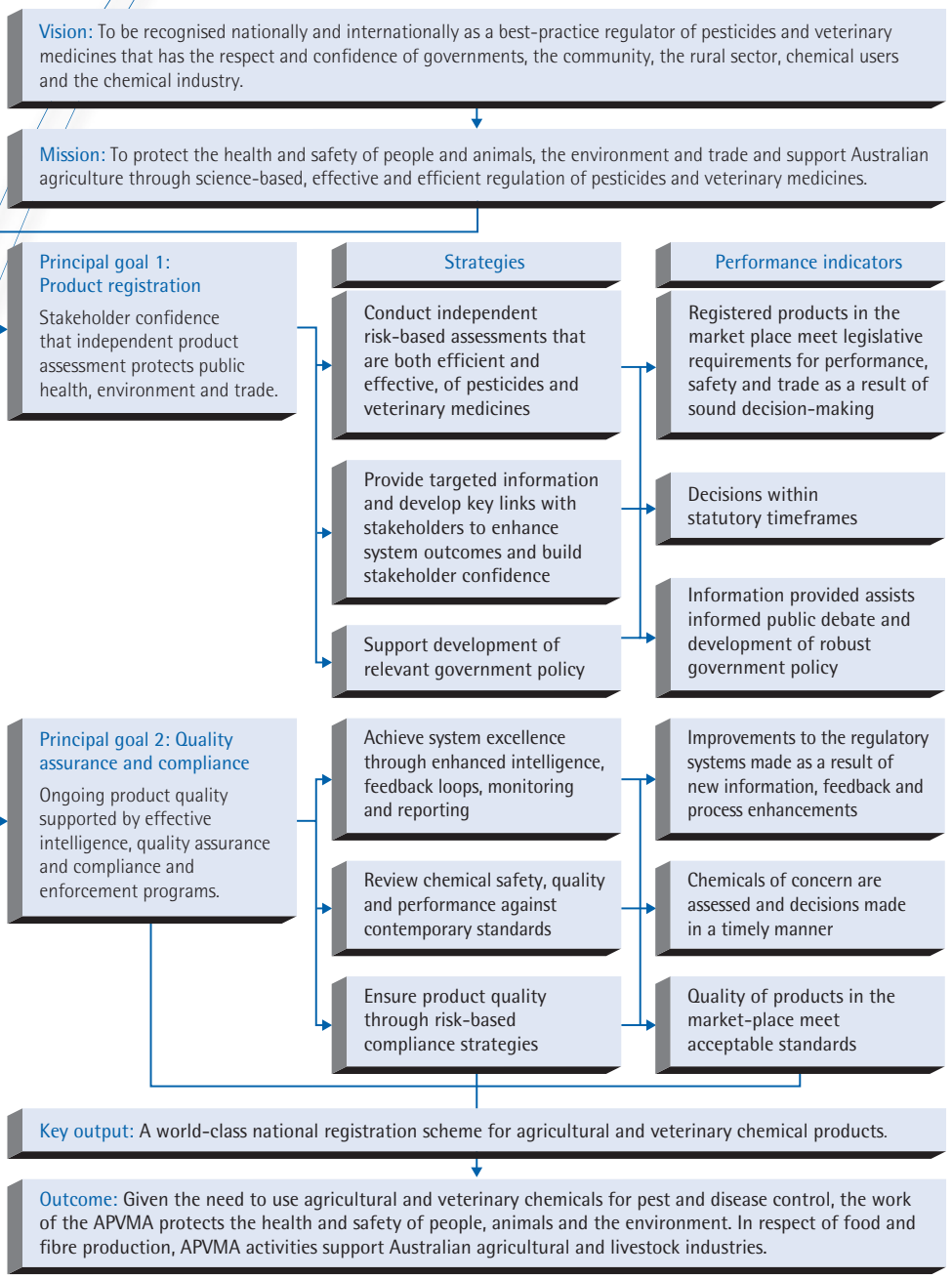
The APVMA achieves results consistent with the agreed outcome and key output through delivery of the principal goals that are supported by a number of strategies. Performance indicators have been identified for each principal goal.

The performance information contained in the next section of this report is presented in line with the outcome-output performance framework structure reflected in the APVMA's Corporate Plan 2003–04 to 2005–06. Progress in the realisation of the key output and principal goals is reported in terms of the nominated performance indicators as well as other major achievements.

The Corporate Plan 2003–04 to 2005–06 and Annual Operational Plan 2003–04 were approved by Senator Troeth in October 2003.

APVMA corporate objectives

Figure 1. APVMA corporate objectives, strategies and performance indicators



2003–04 corporate achievements

Principal goal 1: Product registration

Stakeholder confidence that independent product assessment protects public health, environment and trade

Strategy	Performance
Conduct independent risk-based assessments that are both efficient and effective, of pesticides and veterinary medicines.	■ Finalised 1478 applications for registration, variation to registration or label approval for pesticides (87 per cent within timeframe)
	■ Finalised 960 applications for registration, variation to registration or label approval for veterinary medicines (94.5 per cent within timeframe)
	■ Finalised 834 permit applications for pesticides (84 per cent within timeframe)
	■ Finalised 225 permit applications for veterinary medicines (90 per cent within timeframe)
	■ Changed the APVMA label approval process to comply with October 2003 Agvet Code amendments and incorporate additional label approval requirements
	■ Initiated a number of process improvements that contributed to APVMA-wide productivity gains
	■ Completed a major project to ensure that the APVMA had complete records and current labels for products previously registered by individual States prior to the establishment of the APVMA (then National Registration Authority for Agricultural and Veterinary Chemicals)
	■ Initiated a major reform agenda for minor use including the hosting of a Minor Use forum in November 2003, the establishment of a Minor Use Taskforce and supporting sub-committees, the appointment of a Minor Use Project Officer and the development of a monthly electronic Minor Use Newsletter
	■ Led by APVMA Principal Scientists, made significant progress towards strengthening regulatory science including the development of a peer review program, a standard on good regulatory science practice and a science fellows program
	■ Implemented Service Level Agreements between the APVMA and a number of Australian Government agencies and State and Territory reviewers who provide specialist advice to the APVMA

Strategy	Performance
Provide targeted information and develop key links with stakeholders to enhance system outcomes and build stakeholder confidence.	■ Developed a comprehensive communication plan
	■ Completed a significant web site upgrade. The web site now has three dedicated entry points, one each for community, users and registrants
	■ Participated in many field days, seminars, scientific conferences and forums
	■ Participated in key international forums including OECD, Codex and VICH
	■ Developed an account manager concept where senior officers will manage the ongoing relationships with nominated stakeholders
	■ Conducted an extensive program of CEO visits to key stakeholders
	■ Conducted seminars for registrants including seminars around Australia addressing the impact of legislative amendments
	■ Provided general and targeted information to stakeholders including the *APVMA News*, a community bulletin and the APVMA Gazette
	■ Appropriately managed all media interest (115 media interviews)

Strategy	Performance
Support development of relevant government policy.	■ Provided input to the policy and legislative programs of the Australian Government Department of Agriculture, Fisheries and Forestry
	■ Took part in the activities of the Product Safety and Integrity Committee of the Primary Industries Standing Committee
	■ Contributed to the activities of the Environment Protection and Heritage Council of Ministers' Working Group on the Environmental Risk Management of Chemicals
	■ Worked with Food Standards Australia New Zealand towards streamlining action on the incorporation of maximum residue limits into the Food Standards Code

Principal goal 2: Quality assurance and compliance

Ongoing product quality supported by effective intelligence, quality assurance and compliance and enforcement programs

Strategy	Performance
Achieve system excellence through enhanced intelligence, feedback loops, monitoring and reporting.	■ Maintained ISO accreditation which covers all key APVMA processes
	■ Conducted a thorough review of all registration processes to ensure compliance with the October 2003 legislative amendments
	■ Completed a comprehensive reassessment of chemical review processes and implemented revised processes
	■ Continued a complete revision of the Agricultural and Veterinary Manuals in accordance with the proposed new cost recovery framework
	■ Continued the review and updating of advisory documentation and developed a number of new guidelines
	■ Completed the permits review implementation project
	■ Progressed the development of several low regulatory registration scheme standards
	■ Progressed a major review of the labelling of pesticides and veterinary medicines
	■ Managed the National Hormonal Growth Promotant Monitoring and Control Program
	■ Developed and launched an Adverse Experience Reporting Program for pesticides (AERP *Ag*)
	■ Continued to operate the AERP *Vet*

Strategy	Performance
Review chemical safety, quality and performance against contemporary standards.	■ Managed the ongoing reviews of 33 chemicals
	■ Released four chemical reviews for public comment: arsenic timber treatments, fenitrothion, endosulfan and carbaryl
	■ Announced the review of four chemicals: benomyl, dimethoate, fipronil and omethoate
	■ Implemented new project management procedures for the Chemical Review Program
	■ Developed a range of strategies to better communicate chemical review activities and requirements including targeted information sheets, better utilisation of the APVMA web site and a series of frequently asked questions for high profile reviews

Strategy	Performance
Ensure product quality through risk-based compliance strategies.	■ Introduced a new scheme to ensure the quality of active constituents used in agricultural products
	■ Managed compliance activities including addressing 268 reports of non-compliance, conducting investigations and managing 47 recalls, and clarifying the APVMA's position in relation to advertising of pesticides and veterinary medicines
	■ Successfully managed the Manufacturers' Licensing Scheme (231 licensed manufacturers at 30 June 2004)
	■ Commenced a project to revise the Code of Good Manufacturing Practice (GMP) and develop measures for ensuring GMP compliance by overseas manufacturers
	■ Continued to provide evidence of compliance with the Code of GMP for companies wishing to export veterinary medicines

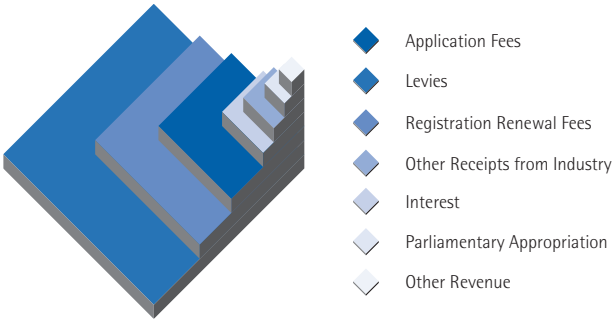
Financial performance

Revenue

APVMA activities are funded on a cost recovery basis with operational revenue being collected mainly from registrants of pesticides and veterinary medicines. Fees are paid to apply for, and annually renew, product registrations. Levies are also paid annually according to the level of disposals of registered products. In 2003–04 industry contributions were 95 per cent of total revenue (2002–03: 95 per cent).

The APVMA's total revenue for 2003–04 was $18.1 million, a reduction of $1.4 million (7.2 per cent) from 2002–03. The fall in revenue is largely due to the effect of the drought on sales of pesticides and veterinary medicines. Revenue in 2003–04 was less than that received in 1999–00 ($18.5 million).

Figure 2. APVMA revenue 2003–04



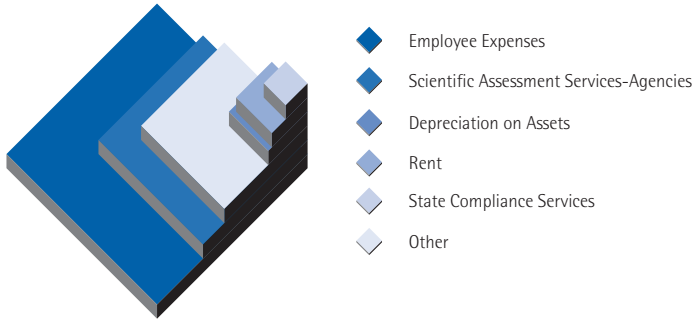
Revenue	$	%
Receipts from Industry:		
Application Fees	2,288,062	13
Levies	9,743,511	54
Registration Renewal Fees	4,702,600	26
Other Receipts from Industry	401,436	2
Interest	727,692	4
Parliamentary Appropriation	170,000	1
Other Revenue	69,420	0
Total Revenue	18,102,721	

Expenditure

Total operating expenses for 2003–04 were $21.6 million, an increase of $1.43 million (7 per cent). The primary reason for the increase is the recognition for the first time of work in progress for external scientific assessment services ($0.538 million) and a provision for doubtful debts for GMP licence fees ($0.291 million). Excluding these technical adjustments, operating expenses increased by $0.604 million (3 per cent), reflecting the APVMA's commitment to tight expenditure control.

In 2003–04 the APVMA delivered a net operating loss of $3.53 million, resulting in a reduction in equity to $4.36 million (2002–03: $7.89 million).

Figure 3. APVMA expenditure 2003–04



Expenditure	$	%
Employee Expenses	11,187,751	52
Scientific Assessment Services-Agencies	5,395,660	25
Depreciation on Assets	762,656	4
Rent	630,551	3
State Compliance Services	237,717	1
Other	3,421,174	15
Total Expenditure	21,635,509	

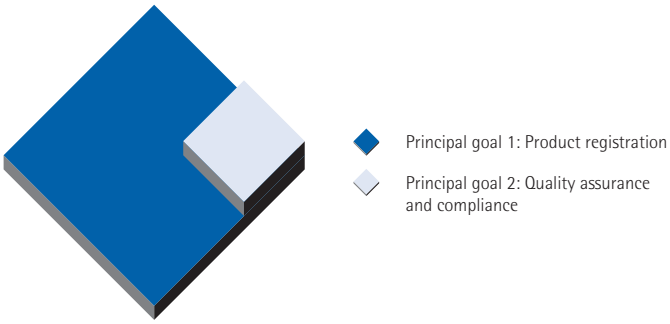
Cost recovery framework

During the year the APVMA continued work to support the Government's proposed revision to its cost recovery framework. In December 2003, the Australian Government Department of Agriculture, Fisheries and Forestry released a draft Cost Recovery Impact Statement for comment. Following consideration of the comments received the Government decided to defer implementation of the proposed new fee structure pending further discussions with key stakeholders.

As a result of strong cost control and better-than-forecast revenue the APVMA has been able to maintain its level of program delivery without the need to make changes to its existing fee structure in 2004–05.

In view of the decision to defer the implementation of a new fee structure a further deficit budget will be unavoidable in 2004–05. This will further reduce the APVMA's equity. It is essential that the issues surrounding the proposed cost recovery framework are resolved allowing new arrangements to commence in 2005–06.

Figure 4. APVMA expenditure by principal goal



Expenditure	$M	%
Principal goal 1: Product registration	18.607	86
Principal goal 2: Quality assurance and compliance	3.029	14
Total	21.636	

Figure 5. APVMA outcome–output expenditure (budget versus actual)

Principal goal 1: Registration

Budgeted cost (PBS* 2003–04) $17.681M

Actual cost $18.607M

Principal goal 2: Quality assurance and compliance

Budgeted cost (PBS* 2003–04) $4.300M

Actual cost $3.029M

APVMA Output

A world-class national registration scheme for agricultural and veterinary chemicals

Budgeted cost (PBS* 2003–04) $21.981M

Actual cost $21.636M

*PBS = Portfolio Budget Statements