

Regulation of Pesticides and Veterinary Medicines

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Background

Pesticides and veterinary medicines are used widely in Australia to protect crops, livestock, and plants from pests and diseases, and to treat animals, including household pets, for illnesses and conditions.¹ In 2004–05, sales of pesticides and veterinary medicines in Australia totalled in excess of \$2.3 billion.

Although pesticides and veterinary medicines provide benefits to users, they can also be hazardous if manufactured or used incorrectly—potentially causing illness or death to humans or animals, or damage to crops and the environment. Also, high levels of chemical residues in food or livestock can jeopardise trade to export markets.

The National Registration Scheme sets out the regulatory framework for the management of pesticides and veterinary medicines in Australia. It is a partnership between the Australian, State and Territory governments. Under the Scheme, the Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible, on behalf of the Australian Government, for:

- registering pesticides and veterinary medicines for use in Australia, having satisfied itself that such products are safe and effective for humans, animals, crops and the environment, and are not a trade risk; and
- assessing the ongoing quality of products following registration, and monitoring compliance with regulations on the importation, manufacture, supply and advertising of pesticides and veterinary medicines, up to the point of retail sale.

State and Territory governments are responsible for controlling the use of registered products, following retail sale. Policy on the management of pesticides and veterinary medicines is formally determined by the Primary Industries Ministerial Council.

The APVMA is a statutory body, governed by a Board of Directors, which operates within the Agriculture, Fisheries and Forestry portfolio. It commenced operations in June 1993, but did not receive full regulatory powers until March 1995.

The APVMA's principal activity is the evaluation of applications to register pesticides and veterinary medicines for use in Australia. These are required to be processed within statutory timeframes. The APVMA also conducts various activities to monitor product quality and compliance. These include a licensing scheme for

manufacturers of veterinary medicines, and a program to review whether products registered in previous years meet contemporary standards of safety and efficacy. In delivering its regulatory functions, the APVMA obtains scientific advice and services from external providers, mainly Australian and State government departments.

The APVMA operates on a cost recovery basis. Its principal source of revenue is a levy on the sale of pesticides and veterinary medicines, which it collects annually from registrants. In 2005–06, the APVMA collected revenue of \$24.3 million, and incurred expenses of \$21.2 million.

Prior to this audit, the Australian National Audit Office (ANAO) completed a performance audit of the APVMA in 1997–98 (then called the National Registration Authority for Agricultural and Veterinary Chemicals).²

1. The term 'pesticides and veterinary medicines' is used to refer to agricultural and veterinary chemical products, as defined in ss. 4-5 of the Agricultural and Veterinary Chemicals Code Act 1994.

2. ANAO Audit Report No. 26 1997–98, Strategic and Operational Management, National Registration Authority for Agricultural and Veterinary Chemicals.

Audit objective and scope

The objective of the audit was to assess whether the APVMA is performing its key regulatory functions effectively. In particular, the audit examined the APVMA's arrangements for:

- planning and overseeing the delivery of regulatory functions;
- registering pesticides and veterinary medicines in a timely manner;
- obtaining external scientific advice to support the registration function;
- monitoring the quality of pesticides and veterinary medicines approved for sale in Australia; and
- administering its cost recovery framework.

Key findings

Governance arrangements (Chapter 2)

The APVMA has met legislative requirements for developing its Corporate and Operational Plans, and seeks input from stakeholders in developing these plans. Legislative requirements, corporate objectives and risk management strategies are aligned in the APVMA's current planning documents. The APVMA monitors its performance against the objectives set out in the Corporate and Operational Plans.

In 2003, the Department of Agriculture, Fisheries and Forestry (DAFF) and the Department of Health and Ageing (DoHA) developed an outsourcing framework for the APVMA. The framework was designed to address recommendations in the previous ANAO report³ and in a National Competition Policy Review⁴ to introduce more contestability into the provision of scientific advice to the APVMA. Under the governance arrangements for the National Registration Scheme, policy affecting the

operations of the APVMA is set by either being formally approved by the Primary Industries Ministerial Council, or through a Ministerial direction. The framework was not established under these arrangements. Also, it was not apparent from the available documentation that the framework has been formally endorsed by the APVMA Board.

To underpin the integrity of its decision making processes, and to provide confidence to stakeholders, the APVMA needs to better manage the risk of actual or perceived conflict of interest. The APVMA's arrangements for managing potential conflict of interest for some external service providers have, until recently, been inadequate. Aspects of the current arrangements also require strengthening. This includes requesting conflict of interest declarations from providers before work commences, and developing appropriate procedures to cover members of consultative committees.

Timeliness of the registration process (Chapter 3)

In processing applications to register pesticides and veterinary medicines, the APVMA is required to meet statutory timeframes for conducting preliminary assessments and finalising formal evaluations. The ANAO found that the APVMA does not have adequate systems and processes to provide assurance that the time recorded to measure its performance is reliable, and reflects actual performance.

The APVMA did not meet its legislative obligation of finalising all applications within statutory timeframes in the period examined by the ANAO (2001–02 to 2005–06). The overall time taken by the APVMA to make registration decisions, which includes applicant time in addressing deficiencies with applications, has increased over this period. Schemes designed to reduce the level of regulatory intervention for lower risk products have not been effective. No products have yet been registered under these schemes.

Although the APVMA has put in place a range of measures to assist applicants in registering products, there is still a high number of deficiencies (errors or omissions) in applications. The APVMA does not have systematic processes for analysing the type and cause of these deficiencies.

Managing external scientific advice (Chapter 4)

The APVMA obtains expert advice to assist it in evaluating applications to register pesticides and veterinary medicines, and to support other regulatory functions. This advice is provided mainly by the Office of Chemical Safety (OCS), the Department of the Environment and Heritage (DEH), State government departments and private consultants.

The APVMA has established adequate formal arrangements with external service providers, with the exception of some State government departments.

OCS and the DEH have generally met the assessment timeframes set by the APVMA. However, almost half of all efficacy and safety assessments finalised in 2004–05 by State government departments or private consultants exceeded the timeframe specified by the APVMA. The ANAO considers the APVMA's arrangements for managing the timeliness of safety and efficacy assessments could be improved by

systematically monitoring reviewer's performance, and analysing the causes of delays, to identify opportunities for improvement.

Since 2001–02, the APVMA has committed in its Service Level Agreements with OCS and DEH to paying a minimum of 80 per cent of the annual budget for estimated services agreed with each agency. This is regardless of whether services of an equivalent value are provided during the financial year. The current arrangement of providing guaranteed minimum funding to OCS and DEH for provision of scientific advice is different from the APVMA's arrangements for engaging other services providers, and stems from its reliance on these agencies for advice. In this context, the APVMA has recently sought to identify other sources of advice, but only for some of the services provided by OCS. No action has been taken to identify alternative providers for the advice currently provided by DEH. It would be timely for the APVMA to assess whether a more contestable approach to the provision of scientific advice would be beneficial and lead to greater efficiencies in the allocation of resources, and thus benefit fee and levy payers.

Monitoring product quality (Chapter 5)

All veterinary medicines must be manufactured to quality standards, and the APVMA has two schemes to confirm that manufacturers comply with these standards—the Manufacturers' Licensing Scheme, and the Overseas Good Manufacturing Practice Scheme.

Manufacturers' Licensing Scheme

A licence is issued to manufacturers by the APVMA under Part 8 of the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code). Under the current licence conditions, the APVMA has not established appropriate access arrangements for staff to undertake regulatory activities. In practice, the APVMA relies on the licence holder granting access when and if requested. The APVMA uses third-party auditors to assess manufacturers' initial and ongoing compliance with quality standards. However, third-party auditors have only been authorised to conduct audits prior to a licence being issued to a domestic manufacturer of veterinary medicines. In practice, third party auditors also undertake audits after the licence has been issued, and appropriate authorisations should be in place.

The APVMA relies on the results of the compliance audits to determine whether licenced manufacturers of veterinary medicines are meeting quality standards. The ANAO found that audits were regularly undertaken after the due date and key documents, such as the audit report, were either overdue or had not been provided to the APVMA. Without these reports, the APVMA has limited assurance that veterinary medicine manufacturers are complying with the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products.

The APVMA was unable to provide documentation (including the audit report) for the audits undertaken by the Therapeutic Goods Administration (TGA) on its behalf. This is contrary to the arrangements in the Memorandum of Understanding between the APVMA and the TGA.

Overseas Good Manufacturing Practice Scheme

Prior to October 2005, the APVMA did not have systems to confirm that overseas manufacturers of veterinary medicines complied with manufacturing requirements following registration. Conditions of product registration are now in place that require the registrant to hold appropriate certifications of compliance for all relevant overseas based manufacturers. The APVMA undertook an initial assessment of evidence of overseas manufacturer compliance in October 2005, and found that its data set was incomplete because registrants did not identify all overseas manufacturers to be used when completing the product application; and/or had not advised the APVMA of changes to the manufacturers they use, after the product was registered.

Quality of pesticides

In September 2005, the APVMA established a program to assess the quality of active ingredients used in the manufacture of pesticides. Records must be held by registrants to prove the quality of the active ingredients used. In February 2006, the APVMA commenced checking these records. The checks found that more than 90 per cent of the records were missing, incomplete or contained errors. Without reliable records, the APVMA can not gain assurance on the quality of pesticides available for sale in Australia.

Reviewing registration decisions

Under the Agvet Code⁵, the APVMA determines whether chemicals approved or registered in previous years meet contemporary standards of safety and efficacy, and do not pose unacceptable risks to people, animals, crops, the environment or to trade. The APVMA established the Chemical Review Program (CR Program) in October 1994 to identify and review chemicals of concern. The APVMA has reasonable arrangements in place to identify chemicals that require review and to prioritise the reviews according to the risks they represent. However, the time taken to progress through the list of chemicals to be reviewed is slow despite efforts being made to improve the timeliness of reviews. Of particular concern is that the risks associated with the use of these chemicals remain. Up to date information on the review program has not been made available to the general public, including users of the affected products.

Cost recovery arrangements (Chapter 6)

The APVMA has taken practical measures to collect the required amount of levy and annual fee revenue. Although there is some misstatement by companies of sales on which the APVMA's levy payments are calculated, the amounts are relatively minor, and the APVMA has taken steps to address these.

The APVMA has established processes to identify the costs of its regulatory activities, to inform the setting of appropriate charges. The cost recovery model is due to be reviewed in 2007–08, as part of a broader review occurring within the Agriculture, Fisheries and Forestry portfolio. This review is timely given some major legislative and organisational changes to the APVMA since its current costing model was last revised in 2003.

The APVMA has generally taken appropriate measures to manage the under or over recovery of revenue. This includes proposing reductions to levy rates when excess revenue has accumulated, and setting funds aside (in a Risk Reserve) to off set an unexpected fall in revenue.

3 ANAO Audit Report No. 26 1997–98, op. cit., paragraph 4.21, p. 37.

4 National Legislation Review: Agricultural and Veterinary Chemicals, Final Report, 13 January 1999, p. ix.

5 Part 2, Division 4.

Overall audit conclusion

The APVMA plays a vital role in the regulation of pesticides and veterinary medicines. Since the ANAO's previous audit in 1997–98, and particularly in recent years, the APVMA has introduced various initiatives to improve the effectiveness of its operations. However, key programs to monitor the quality of pesticides and veterinary medicines, such as the Manufacturers' Licensing Scheme and the Chemical Review Program, could be better administered. Greater emphasis needs to be given to compliance programs and to completing chemical reviews in order for the APVMA to provide assurance that manufacturers of pesticides and veterinary medicines are meeting the required standards, and that products approved for sale in Australia are safe and effective. The APVMA is also not meeting its obligation to finalise all applications within statutory timeframes. This increases the cost of regulation, for both the APVMA and applicants, and impacts on users' access to pesticides and veterinary medicines.

The ANAO considers that, to deliver its regulatory functions more effectively, the APVMA needs to address some key issues relating to the broader management of the National Registration Scheme. These include reviewing the current arrangements for sourcing expert scientific advice to inform its registration decisions, and the role of State and Territory government agencies in conducting compliance monitoring activities on its behalf. In addition, the APVMA should examine options for establishing more effective arrangements for regulating pesticides and veterinary medicines deemed to be lower risk. Such arrangements should allow the APVMA to utilise its resources better, potentially resulting in improved timeframe performance for determining applications.

The ANAO has made six recommendations aimed at improving the APVMA's regulation of pesticides and veterinary medicines.

APVMA response

The APVMA welcomes the ANAO report and accepts the six recommendations of the report. The recommendations will assist our efforts to continue to strengthen performance as an efficient and effective regulator. Actions to implement the recommendations are underway.

With respect to Recommendation 1, the APVMA will strengthen existing arrangements for managing potential conflicts-of-interest in the identified areas. The APVMA will implement Recommendations 2 and 3 by building on current initiatives to manage and report on timeliness of processing registration applications and by more systematic analysis and communication to the chemical industry of types of deficiencies in their applications. Current arrangements for procuring external scientific advice will be reviewed to implement Recommendation 4. The operation of the APVMA's Manufacturers' Licensing Scheme will be strengthened through implementation of Recommendation 5. With respect to Recommendation 6, the APVMA will assess current approaches to chemical review and disseminate more comprehensive information on reviews to stakeholders.