CHAPTER 1
CEO'S REPORT AND OUTLOOK

The APVMA's *Operational Plan 2008–09* foreshadowed that this would be an important year for us. It was a year in which we concentrated on embedding the executive management governance framework into our operations, supported by the advice and assurance from the Advisory Board and Audit Committee. It was a year in which the organisation focused on developing staff expertise and leadership skills while promoting a culture of transparency, responsiveness and predictability.

High standards and timely scientific evaluation are our priority. Efficiencies were gained and consistency strengthened through increased national and international collaboration, including in the area of Minor Use. We increased compliance field operations, and we engaged in and responded to high levels of media and community interest in emerging regulatory issues.

We actively joined in the Australian Government's regulatory reform agenda, investing in informing early-harvest as well as long-term reform to capitalise on opportunities to deliver improved efficiency and effectiveness of our operations.

The three key strategic themes of stakeholder confidence, operational excellence, and informing policy against which we have previously reported remain a useful framework for considering other progress and achievements.

Stakeholder confidence

In 2008–09, the APVMA developed a new corporate plan for the years 2009 to 2012. Stakeholders were formally invited to provide input to the plan and the Advisory Board provided valuable advice about the current business environment, opportunities and challenges, and strategic considerations. In accordance with this advice, the plan identifies enhancing the reputation of the APVMA as the key objective. The plan provides the direction for APVMA's activities for the next three years, as is consistent with the *Operational Plan 2009–2010* with its focus on strategies and activities that will enhance stakeholder confidence.

Beginning in late 2007–08 and continuing throughout 2008–09, the APVMA conducted a review of its cost recovery arrangements. We used this opportunity to showcase best-practice stakeholder consultation and engagement—a key priority. The review focused on compliance with the established cost recovery policy framework and improving service standards.

Many demands have been put on the APVMA by the pace of reform, staff movements, and responding to new and emerging issues. As a result, some of our core activities, such as delivering on registration timeframes, have been under intense pressure. During 2009–10, we will therefore concentrate on core work with a focus on performance, our people, and on technical and ethical excellence.

The APVMA regulatory science quality program was enhanced in this year. The program was expanded to include the formation of a Veterinary Medicines Expert Advisory Panel (VMEAP). We also created the new role of Visiting Scientist. The concept of the panel is that it brings together Science Fellows with specific expertise to address particular regulatory science problems. Visiting Scientists deliver specialised training and are also available to provide advice to evaluators on scientific risk assessments. We also appointed a number of new Science Fellows—they are eminent national and international scientists who provide high-level independent advice on complex and contentious regulatory issues; assist in the development of regulatory science policy; provide advice in relation to staff training; and speak at APVMA Science Fellows symposia. These initiatives assist us to enhance the quality of regulatory science and build public confidence in the APVMA.

Operational excellence

During 2008–09, the APVMA maintained its traditionally strong commitment to operational excellence. The APVMA responded to need for greater transparency and predictability on registration decisions by developing and piloting a project management approach for major applications, allowing applicants to submit certain parts of the dossier at a later time (this is called timeshift) and encouraging pre-submission meetings to improve understanding of application requirements. During the 2008–09 year, the APVMA worked with several overseas regulatory agencies in joint reviews or work sharing for assessments of new pesticide active constituents.

The timeframe performance for registration applications was less than 100 per cent (Pesticides Program 85 per cent; Veterinary Medicines Program 88 per cent) because of the priority the APVMA places on maintaining consistently high standards of rigour, quality control and quality of decisions, despite the impact of staff turnover on the APVMA's capacity to address the variable workload and increased administrative burden. The good timeframe results overall are due to the sustained and concerted effort of our very dedicated staff.

A key priority was to rebuild and restructure our chemistry expertise following the loss of key staff to other organisations. This task was substantially completed during the year, and it led to a very pleasing increase in productivity. A feature of the restructure was the creation of a Pesticide Chemistry team in the Pesticides Program and a Pharmaceutical Chemistry team in the Veterinary Medicines Program.

During the year, the APVMA continued to invest human and financial resources into delivering greater efficiencies through enhanced electronic business initiatives. Work commenced on the development of an internal Electronic Application and Registration System (EARS), which will replace existing legacy systems, and on an Online Levy and Renewals system to replace external service. Server virtualisation was adopted as a strategy to deliver enhanced performance of IT infrastructure and the decision was made to move to a bimonthly electronic APVMA Gazette.

The APVMA is pleased with its achievements in the chemical review area, having achieved a balance of mandatory and voluntary variations to registration conditions or voluntary cancellations in line with the target to complete five review decisions during the year.

Informing policy

The year has been an extraordinarily busy one. The Council of Australian Governments (COAG) has set an ambitious reform agenda following the Productivity Commission's August 2008 research report into chemicals and plastics regulation. These reforms include addressing some quite specific 'early harvest' policy reforms as well as broad initiatives that have led to a review of the whole National Registration Scheme. The latter initiative includes consideration of a single national framework to improve the efficiency and effectiveness of the regulation of pesticides and veterinary medicines, and it has the potential to transform the regulatory system in Australia.

In addition to the COAG processes, the APVMA has continued to work with policy-makers to further improve and refine the alignment of the National Registration Scheme with contemporary needs and demands. We have sought to maintain national and international relationships to produce efficiencies in the delivery of our regulatory functions where possible. The APVMA believes that there are further opportunities to achieve improvements in the efficiency and effectiveness of chemicals regulation. The COAG reform agenda provides a vehicle for such opportunities to be explored and realised.

In 2008–09, the APVMA has continued activities to complete its implementation of the ANAO recommendations. At 30 June 2009, four of the six recommendations had been implemented and the development work for a further recommendation was finalised and implemented early in the 2009–10 financial year. The remaining recommendation has been partially addressed, and further progression of that reform has been delayed pending the overall review of the National Registration Scheme.

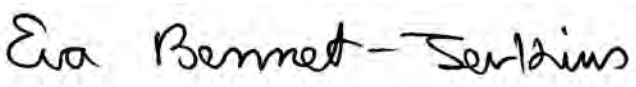
The future

The APVMA is pleased with its achievements this year and of our response to internal as well as external challenges and opportunities. I am proud of the dedication and professionalism of our staff and their commitment to high standards. I am grateful for the support and expert counsel provided by the Advisory Board throughout the year and for the independent assurance provided by the work of the Audit Committee.

Changes in the external environment and pressures for faster decisions, greater transparency, and building public confidence continue to be challenges to the APVMA. Accordingly our emphasis will be to foster stability and resilience, to consolidating key priorities and focus on core business while embracing the Australian Government's regulatory reform agenda.

Our future is about enhancing our reputation and promoting confidence through consistent and predictable decisions, raising the level of awareness of how our activities protect people, the environment and trade, engaging with other government agencies (national and international), valuing our people and investing in the development of our systems.

The review of the cost recovery arrangements aims to provide a sustainable and reliable source of revenue that will provide the APVMA with the capacity to meet these objectives and deliver a quality regulatory framework. To deliver on these objectives, the APVMA will place particular emphasis on ensuring that the improvements sought by strategies and activities are achieved.



Dr Eva Bennet-Jenkins

Chief Executive Officer

Outlook

The coming year will be a year of consolidation for the Australian Pesticides and Veterinary Medicines Authority (the APVMA) as it continues to manage changes to the governance framework and as it continues to implement the Australian Government's regulatory reform agenda. In 2008–09, the APVMA responded to new and emerging issues while meeting the expectations of a diverse group of stakeholders. As a result, some core activities, such as delivering on registration timeframes, have been under intense pressure. The APVMA's focus for 2009–10 is to raise performance and foster stability within available resources and the operating environment.

The 2009–10 financial year will be the year that the APVMA concentrates on core work, the reform agenda of the Council of Australian Governments (COAG), and finalising recommendations from the Australian National Audit Office's audit report. The APVMA will focus on performance and our people, and pursue technical and ethical excellence.

The APVMA started a review of its cost-recovery arrangements in 2007–08, and continued the review throughout 2008–09. This was part of the scheduled review of the Agriculture, Fisheries and Forestry Portfolio. Changes to the cost recovery arrangements will be phased in from 2009–10, and all changes are proposed to be in place by July 2011 (subject to legislative changes). These changes will underpin the efficiency and effectiveness of APVMA business.

The framework of the *Operational Plan 2009–2010* identifies the following priorities for the APVMA, given its available resources:

Stakeholder confidence

- **Stakeholder engagement**: complete the stakeholder engagement strategy and implement key initiatives
- **Compliance**: finalise the Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (Ag QA Scheme) and form the legislation review working group
- **Scientific quality**: enhance regulatory science quality within the APVMA

Operational excellence

- **Predictability**: enhance responsiveness and predictability of the evaluation process for new and existing chemicals and completion of applications within legislative timeframes
- **Value our staff**: enhance leadership and risk management skills
- **External scientific service provider performance**: improve external service provider quality and cost effectiveness including the use of international reports and work share evaluations
- **Cost recovery**: implement system and process changes

Informing policy

- **COAG agenda**: progress initiatives under the regulatory reform agenda including input to the development of a scheme for national control of use

Other activities

- Finalise the Australian National Audit Office Audit recommendations
- Advance the Electronic Applications and Registration System (EARS) initiative