



Appendices

Appendix A: APVMA Board of Directors

This APVMA Board of Directors was appointed on 16 October 2005 for a term expiring on 15 October 2008. The Chairperson was appointed for a term expiring on 16 October 2007. The Board of Directors ceased to exist on 30 June 2007 as new governance arrangements for the APVMA commenced on 1 July 2007.

The Board met six times in 2006–07, in August, October and November 2006 and in February, May and June 2007. Directors' attendance at Board meetings is shown in Table A1.

Table A1: Attendance at APVMA Board meetings 2006–07

| Name | Meetings attended | Meetings eligible to attend |
|---|-------------------|-----------------------------|
| Dr Kevin Sheridan AO (Chairperson reappointed 16 October 2005) | 5 | 6 |
| Dr Lyn Fragar AO (reappointed as a Director 16 October 2005; reappointed as Deputy Chairperson 25 October 2005) | 6 | 6 |
| Dr Catherine Hollywell (reappointed as a Director 16 October 2005) | 4 | 6 |
| Mr Hutch Ranck (reappointed as a Director 16 October 2005) | 5 | 6 |
| Ms Mara Bún (reappointed as a Director 16 October 2005) | 6 | 6 |
| Mr John Mollison (Director appointed 9 December 2005) | 6 | 6 |
| Mr Stephen McCutcheon (Director appointed 16 October 2005) | 4 | 6 |
| Mr Wayne Cornish (Director appointed 16 October 2005) | 4 | 6 |
| Mr Claude Gauchat (Director appointed 16 October 2005) | 6 | 6 |

Contact: Alan Hill, Executive Officer, APVMA Board, telephone 02 6210 4786.

Declared interests

For the purposes of the CAC Act, Directors were required to declare any potential material personal interests in relation to any matters before the Board. Interests so declared were considered and determined by the Board in accordance with APVMA corporate governance procedure and with reference to advice from the General Counsel. Declarations made by Directors in 2006–07 and the related Board determinations are contained in Table A2.

Table A2: Declaration of Interests

| Board Meeting | Declaration |
|----------------------------|---|
| APVMA21 (8 August 2006) | <p>a. Mr Cornish declared his interest in the update on the Chemical Review of 2,4-D as Chair of the National Farmers' Federation (NFF) Farm Chemical Committee.</p> <p>b. Mr McCutcheon declared his interest in the update on the Uhrig review of corporate governance arrangements and in the discussion of security sensitive chemicals issues as Executive Manager, Product Integrity, Animal and Plant Health Division, Australian Government Department of Agriculture, Fisheries and Forestry.</p> <p>The Board noted that that neither Director's declaration constituted a material personal interest for the purposes of the <i>Commonwealth Authorities and Companies Act 1997</i> and determined that those Directors may be present for discussions and participate in deliberations relating to the above matters.</p> |

| | |
|---------------------------------------|---|
| <p>APVMA22 (12 October 2006)</p> | <p>a. Mr Cornish declared his interest relating to any discussions concerning the review of 2,4-D in his role as Chair of the National Farmers' Federation (NFF) Farm Chemical Committee.</p> <p>The Board determined that Mr Cornish does not have a material personal interest in this matter for the purposes of the <i>Commonwealth Authorities and Companies Act 1997</i>.</p> <p>b. Dr Hollywell and Mr Mollison declared their interest in the 1080 chemical review findings; Dr Hollywell as Director, Agriculture Development with the Victorian Department of Primary Industries and Mr Mollison as Registrar of Chemical Products with the Tasmanian Department of Primary Industries and Water.</p> <p>The Board noted that those two state entities are registrants or permit holders of 1080 products and determined that for the purposes of the <i>Commonwealth Authorities and Companies Act 1997</i> both Dr Hollywell and Mr Mollison may participate in discussions, but would abstain from voting on any decisions relating to the review of 1080.</p> |
| <p>APVMA23 (30 November 2006)</p> | <p>a. Mr McCutcheon declared his interest in any discussions concerning the Uhrig and security sensitive chemicals in his role as Executive Manager, Product Integrity, Animal and Plant Health Division, Department of Agriculture, Fisheries and Forestry.</p> <p>The Board determined that Mr McCutcheon does not have a material personal interest in these matters for the purposes of the <i>Commonwealth Authorities and Companies Act 1997</i>.</p> |
| <p>APVMA24 (20 February 2007)</p> | <p>a. Mr Ranck declared his interest in any discussions concerning the proposed review of carbendazim and thiophanate-methyl in his role as Managing Director of Du Pont (Australia) Ltd, which holds an active constituent approval for carbendazim.</p> <p>b. Dr Fragar declared her interest in any discussions concerning the review of diazinon in her role as Director of the Australian Centre for Agricultural Health and Safety, which undertook scientific trials upon which the Board will deliberate in making decisions concerning the review of diazinon.</p> <p>The Board was advised that Mr Ranck and Dr Fragar do each have a potential material personal interest in these matters for the purposes of the <i>Commonwealth Authorities and Companies Act 1997</i> and determined that Mr Ranck and Dr Fragar may be present for discussions, but may not participate in any vote on matters for which they have declared a material personal interest.</p> |
| <p>APVMA25 (2 and 4 May 2007)</p> | <p>a. Dr Fragar declared her interest in the discussion relating to review of diazinon as Director of the Australian Centre for Agricultural Health and Safety which undertook the scientific trials to generate worker exposure data used in the diazinon risk assessment.</p> <p>The Board was advised that Dr Fragar has a potential conflict of interest for the purposes of the <i>Commonwealth Authorities and Companies Act 1997</i> and determined that Dr Fragar may be present for discussions but may not vote on matters concerning the proposed suspension of diazinon labels.</p> |
| <p>APVMA26 (28 June 2007)</p> | <p>No declarations.</p> |

Indemnities and insurance

The APVMA has provided indemnity to each Director and several of the APVMA's staff.

The APVMA maintains Directors' and Officers' liability insurance as set out in Table A3. The nature of the liabilities covered and the amount of premium payable under the contract of insurance are confidential under the terms of the policy.

Table A3: Indemnities and insurance for APVMA Directors and Officers 2006–07

| Name | Indemnity | Directors' and Officers' liability insurance |
|--|-----------|--|
| Dr Kevin Sheridan AO, Chairperson | Y | Y |
| Dr Lyn Fragar AO, Deputy Chairperson | Y | Y |
| Dr Catherine Hollywell, Director | Y | Y |
| Mr John Mollison, Director | Y | Y |
| Mr Wayne Cornish, Director | Y | Y |
| Mr Hutch Ranck, Director | Y | Y |
| Ms Mara Bún, Director | Y | Y |
| Mr Claude Gauchat, Director | Y | Y |
| Mr Stephen McCutcheon, Director | Y | Y |
| Dr Joe Smith, CEO | Y | Y |
| Mr Martin Holmes, Program Manager, Veterinary Medicines | Y | Y |
| Dr Tim Dyke, Program Manager, Quality Assurance and Compliance | Y | Y |
| Mr Tony de la Fosse, Program Manager, Corporate Services | Y | Y |
| Mr James Suter, General Counsel | Y | Y |
| Dr Eva Bennet-Jenkins, Program Manager, Pesticides | Y | Y |
| Dr Trevor Doust, Program Manager, Chemistry and Residues | Y | Y |

Audit Committee

The primary objective of the Audit Committee is to assist with the Board's responsibilities relating to the APVMA's annual budget, financial accounting and reporting practices.

The APVMA Board appointed an Audit Committee on 30 November 2006. The committee comprised Dr Lyn Fragar AO (Chairperson), Mr Hutch Ranck and Dr Catherine Hollywell. The Board also nominated Mr Gauchat and Mr Mollison as alternate Audit Committee members should either Mr Ranck or Dr Hollywell be unavailable to attend an audit meeting.

Audit Committee meetings in 2006–07 were held on 6 August and 24 October 2007 and on 20 March and 19 June 2007 to coincide with key financial year milestones for provision of advice and reports to the Board. Attendance at Audit Committee meetings is shown in Table A4.

In accordance with its Charter, the Audit Committee provided an Annual Report on its activities during the previous twelve months to the Board at APVMA26 on 28 June 2007.

Table A4: Attendance at APVMA Audit Committee meetings 2006–07

| Name | Meetings attended | Meetings eligible to attend |
|--------------------------------------|-------------------|-----------------------------|
| Dr Lyn Fragar AO (Audit Chairperson) | 4 | 4 |
| Dr Catherine Hollywell | 4 | 4 |
| Mr Hutch Ranck | 1 | 4 |
| Mr Claude Gauchat* | 3 | 3 |
| Mr John Mollison* | 0 | 3 |

* Alternative committee member. Only required to attend in the absence of a primary committee member.

Appendix B: Committees

Community Consultative Committee

Purpose

The APVMA's Community Consultative Committee (CCC) provides a direct link between the national agvet chemical regulator and the Australian community. It provides a forum for two-way communication between the APVMA and community representative organisations that have an interest in the way pesticides and veterinary medicines are regulated. The Committee addresses issues raised with it by the community as well as those referred to it by the APVMA. The committee met four times in 2006–07; in August, November, March and June.

Terms of reference

The CCC's terms of reference require it to:

- communicate community views to the APVMA on a range of issues concerning pesticides and veterinary medicines
- encourage informed community debate by conveying information from the APVMA to community networks and explaining the operations and processes of the APVMA to the community
- convey community concerns to the APVMA about pesticides and veterinary medicines
- recommend to the APVMA further work that might be undertaken to resolve issues of community concern relating to the registration of pesticides and veterinary medicines
- advise on matters referred to it by the APVMA.

Issues considered

At each meeting, members report to the APVMA about committee-related activities as well as details of any important issues of concern. The APVMA provided reports to each meeting detailing registration and review activities for pesticides and veterinary medicines as well as quality assurance and compliance matters.

It is pleasing to note that the APVMA has embraced a number of CCC-generated ideas. These includes work on:

- developing guidelines for registration of reduced risk chemistry and the conduct of a users survey to explore impediments to uptake of reduced risk chemistry and farming practices; and the
- developing a community engagement charter as part of the APVMA's wider stakeholder engagement strategy.

Highlights

Significant achievements for the committee during 2006–07 were:

- progress on the development of a consumer guide on the relative harshness of chemicals in the home
- commencement of a report on the effectiveness of the adverse experiences reporting program for agricultural products

- active participation in the APVMA labelling review activities
- organising a forum to discuss the atrazine review
- development of a forward looking three-year work plan focusing on emerging trends in risk assessments and reduced risk approaches.

Table B1: Membership and attendance at Community Consultative Committee meetings 2006–07

| Member | Affiliation | Meetings eligible to attend | Meetings attended |
|-------------------------|---|-----------------------------|-------------------|
| Ms Jenni Mack (Chair) | Australian Consumers' Association | 4 | 4 |
| Mr Sam Beechey | Australian Workers' Union | 4 | 3 |
| Ms Jo Immig | National Environmental Consultative Forum | 4 | 4 |
| Mr Peter Cone | National Farmers Federation | 4 | 4 |
| Dr Liz Hanna | Public Health Association of Australia | 4 | 3 |
| Mr Neville Prowse-Brown | Australian Landscape Trust | 4 | 4 |
| Ms Julie Buckley | TAFE NSW | 4 | 3 |
| Mr John Temperley | Farmsafe Australia Inc | 4 | 3 |
| Mr Joe Elbustani | Greenhouse Vegetables Association, NSW Farmers' Association | 4 | 3 |

In 2006–07, Dr Eva Bennet-Jenkins, Program Manager Pesticides, was APVMA advisor to the Committee for the August, November and March meetings. Dr Tim Dyke, Program Manager Quality Assurance and Compliance, was APVMA Advisor for the June meeting. Secretariat: Dr Simon Cubit, Manager Public Affairs, telephone 02 6210 4869

Registration Liaison Committee

The Registration Liaison Committee (RLC) is the main consultative forum between the APVMA, representatives of the state and territory signatories to the NRS and other relevant Australian Government agencies. The RLC met in Canberra in September 2006 and March 2007, and by teleconference in November 2006 and June 2007.

Purpose

The main purpose of the RLC is to provide a forum for the development and operational coordination of the NRS and for consultation on the development of operational policies, guidelines and protocols in both the APVMA and the signatory organisations, to allow effective alignment of the agvet chemical control objectives of the APVMA and states and territories.

Terms of reference

The terms of reference of the RLC are to:

- align the outputs of the APVMA's registration processes and the chemical management objectives of the states and territories
- develop operational policies with regard to the operation of the NRS including those dealing with registration (including labelling), regulation and appropriate use of agricultural and veterinary chemicals
- provide feedback on state and territory views on these issues and particularly their impact on chemical users and the responsibilities of regulators
- address specific operating policy issues as necessary
- provide input to operational planning priorities
- provide input to existing chemical review priorities.

Issues considered

The RLC agendas provide for updates on operational activities, consultation and consideration of topical issues and progression of matters contained in the RLC/ APVMA Work Plan. The APVMA's reports in 2006–07 included pesticides and veterinary medicines registration activities, permits and minor use, quality assurance, compliance and the progress of chemical reviews. The states, territories, other Australian Government departments and New Zealand provided reports on policy, control of use and related regulatory activity within their jurisdictions.

Highlights

Key topics and issues the RLC considered during the reporting period included:

- in-principle endorsement of a proposed draft MOU between the APVMA and the states and territories to formalise existing operational arrangements
- seeking RLC members' contributions to the development of strategic reforms aimed at enhancing compliance enforcement mechanisms and improving the alignment of legislative provisions for product assessment with conditions that apply after a product is registered
- accepting a request for a state or territory representative to regularly attend meetings of the APVMA's Industry Liaison Committee
- planned further reform of the APVMA's efficacy assessment framework allied to meeting the ANAO Performance Audit recommendations including engagement of external pesticide reviewers, clarifying data requirements and assessment criteria, and developing improved timeliness and quality performance indicators
- seeking a state or territory nomination to undertake the primary efficacy evaluation of an international work sharing arrangement between the APVMA and other members of the OECD Working Group on Pesticides
- progress updates and input to the RLC/APVMA Work Plan including high priority projects for developing assessment criteria and data requirements for animal and post-harvest chemical dip disposal, the Labelling Code Working Group, Minor Use reforms, regulation of off-label quarantine treatments and development of APVMA manuals and guidelines

- development of an APVMA brochure to provide up to date information on the use of pesticides in and around school buildings
- the APVMA's report on the effectiveness of the Restricted Chemical Products scheme noting that the report will assist with the development of a national framework for declaring Restricted Chemical Products
- the progress of APVMA chemical reviews and the development of environmental risk hazard priority listing criteria for review chemicals
- commencement by the APVMA of a detailed review of Service Level Agreements and related arrangements for efficacy assessments between the APVMA and the relevant states and territories
- outcomes of the APVMA's Review of Consultative Committees including changes to the RLC's Terms of Reference
- APVMA progress with the implementation of the ANAO Performance Audit recommendations and preparations for the transition to new APVMA governance arrangements from 1 July 2007
- gaining members' in-principle support for a proposal by the University of Queensland's Centre for Pesticide Application and Safety to conduct advanced spray drift modelling and to a request that the states and territories investigate providing project funding from within their jurisdictions
- a range of other operational matters including agreement on a consistent approach to interstate quarantine permits, proposals to clarify the definition of veterinary chemical products, proposed development of regulatory approaches to chemicals in organic agriculture, approval of amended commodity names in the MRL standard, operational policy relating to labels claims for exotic pests and diseases, the potential regulatory impacts of New Zealand's introduction of mandatory hazard label statements and updates on issues relating to Multiple Chemical Sensitivity.

Attendance at Registration Liaison Committee meetings is shown in Table B2.

Table B2: Membership and attendance at Registration Liaison Committee meetings and teleconferences 2006–07

| Member | Organisation | Meetings eligible to attend | Meetings attended |
|---|---|-----------------------------|-------------------|
| Mr Martin Holmes (Chairperson) | APVMA | 4 | 4 |
| Mr David Power | Environment Protection, ACT Chief Minister's Department | 4 | 2 |
| Mr Lee Cook | NSW Department of Primary Industries | 4 | 4 |
| Mr Andrew Hawkins Mr Roger de Keyzer | NSW Department of Environment and Conservation (now the Department of Environment and Climate Change) | 4 | 2 1 |
| Ms Sue Duncan | Department of Primary Industries, Vic. | 4 | 4 |
| Mr John Kassebaum Ms Petra Lennon | Primary Industries and Resources SA | 4 | 3 1 |
| Mr Ian Parr | Department of Primary Industries and Water, Tas. | 4 | 4 |
| Mr Vlad Kawaljenko | Department of Primary Industry, Fisheries and Mines, NT | 4 | 3 |
| Mr Wayne Thompson | Department of Primary Industries and Fisheries, Qld | 4 | 4 |
| Mr Chris Sharpe | Department of Agriculture and Food, WA | 4 | 2 |
| Dr Martin Matisons | Department of Health, WA | 4 | 3 |
| Ms Maree Zinzley Ms Trish Whitaker | Agricultural Chemicals and Veterinary Medicines Group, New Zealand Food Safety Authority | 4 3 | 2 1 |
| Dr Geoff Thompson | Office of Chemical Safety, Australian Department of Health and Ageing | 4 | 2 |
| Mr Greg Plummer | Chemical Assessment Section, Australian Department of the Environment and Water Resources | 4 | 3 |
| Dr Ingo Ernst | Aquatic Animal Health Unit, Australian Department of Agriculture, Fisheries and Forestry | 1 | 0 |

Contact: Alan Hill, Legal and Governance Program, telephone 02 6210 4786

Industry Liaison Committee (ILC)

Purpose

The Industry Liaison Committee (ILC) was established in 1995 and is the main consultative forum between the APVMA and peak chemical industry organisations representing registrants.

The purpose of the ILC is to:

- provide a forum for formal consultation and discussion with peak chemical industry bodies on APVMA operating policies and programs
- enhance co-operation in the management of the registration process and post-registration programs.

Terms of reference

The committee's terms of reference are to:

- progress the development of agreed standards and procedures for the assessment of agvet chemicals
- obtain the views of industry members on issues of an operational, technical or strategic nature
- provide industry input to APVMA operational planning processes
- identify opportunities for regulatory reform within the existing framework
- enable reporting by the APVMA to industry of its performance
- address specific operating policy issues through working groups
- consider the impact of proposed macro-policy changes on APVMA operations and implications for industry.

Issues considered

- certain residue violations in stock feed and food for human consumption
- reducing chemistry data for some applications
- reform of compliance strategic role
- labelling reform
- Minor Use: reform initiatives such as the Minor Use Liaison Office (MULO)
- Globally Harmonised System of Classification and Labelling of Chemicals (GHS)
- reform of APVMA governance structure following the Uhrig review
- reform of external efficacy assessment process
- the enhanced chemical review consultation process
- implementation of ANAO audit recommendations
- development of an online application submission system
- state control-of-use legislation

- impact on APVMA of the National Framework for Chemicals Environmental Management in Australia (NChEM)
- review of the APVMA's registration process
- COAG ministerial taskforce on chemicals regulation (the 'Banks Report')
- APVMA hosted chemistry seminars to improve the quality of applications
- spray drift project work plan.

Attendance at ILC meetings for 2006–07 is shown in Table B3.

Table B3: Membership of and attendance at Industry Liaison Committee meetings 2006–07

| Member | Organisation | Meetings eligible to attend | Meetings attended |
|----------------------------|---|-----------------------------|-------------------|
| Dr Joe Smith (Chairperson) | APVMA | 3 | 3 |
| Mr Geoff MacAlpine | ACCORD Australasia | 3 | 3 |
| Ms Kathy Nolan | | 3 | 3 |
| Ms Dusanka Sabic | | 1 | 1 |
| Mr Lindsay Showyin | Aerosol Association of Australia Inc. | 3 | 3 |
| Mr Philip Fleming | | 2 | 1 |
| Mr Justin Golding | | 2 | 2 |
| Dr Peter Holdsworth | Animal Health Alliance | 3 | 2 |
| Mr Bob Cranna | (Australia) Ltd | 1 | 1 |
| Ms Paula Matthewson | CropLife Australia | 3 | 3 |
| Dr Adrian Harris | | 3 | 3 |
| Mr John Firth | Generic Agricultural Chemical Association | 3 | 2 |
| Mr Kevin Bodnaruk | Nursery and Garden Industry Australia | 3 | 2 |
| Mr Bernard Lee | Plastics and Chemicals Industries Association | 3 | 1 |
| Mr Andrew Wells | | 1 | 1 |
| Ms Stephanie Leach | | 1 | 1 |
| Mr Paul Simons | Swimming Pool and Spa Association of Australia | 3 | 0 |
| Mr Robert Schufft | The Veterinary Manufacturers and Distributors Association Ltd/Pet Industry Association of Australia | 3 | 3 |
| Mr Ian Saunders | | 1 | 1 |
| Mr Jim Adams | | 3 | 3 |
| Mr Neil Sammons | | | |

Secretary: David Hutchison, telephone 02 6210 4748

Industry Technical Committee

Purpose

The Industry Technical Committee (ITC) supports the Industry Liaison Committee (ILC) by addressing technical issues affecting regulatory policy, programs and performance. Membership of the ITC is drawn from industry groups represented on the ILC and from other specialist scientific and technical groups. In 2006–07, the ITC met in Canberra in September 2006, February 2007 and June 2007.

The objectives of the ITC are to:

- provide input to the development of operating procedures and publications
- review and consider the technical work of the APVMA
- address specific technical issues through working groups.

Terms of reference

The ITC was created by the ILC to:

- improve the functioning of the ILC for industry and the APVMA by dealing with specific technical issues
- provide a forum for peak industry and technical/professional bodies to progress technical, administrative and other relevant issues.

Issues considered

Issues before the ITC in 2006–07 included:

- reports of working group/consultation
- the APVMA's Adverse Experience Reporting Program
- data protection
- new guidelines and operational policies
- implementation of ANAO recommendations including management of conflict of interest for members of APVMA consultative committees
- proposed revision to safety and efficacy requirements for vaccines, where data are generated overseas
- Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
- permit for consumer trials
- trial protocol applications
- stock foods which claim to prevent diseases or conditions
- approval of new active constituents
- approving a single representative label for a range of pack sizes
- rejection of applications at screening
- draft policy on the registration of selenium products for use in sheep
- development of an Agricultural Practices Handbook
- minor use
- update on the Working Group on Proposed Compliance Legislative Reform

- proposed APVMA operational policy on tablet dosages for cats
- evidence of GMP compliance by overseas manufacturers
- update of ‘approved persons’ definition
- reduced chemistry data requirements
- natural health products—are they veterinary medicines?
- inter-row crop spraying
- nursery plant definitions/classifications
- proposed changes to herbicide mode of action groups
- duplication of requirements by statutory organisations.

Table B4: Membership of and attendance at Industry Technical Committee meetings 2006–07

| Member | Organisation | Meetings eligible to attend | Meetings attended |
|---|---|-----------------------------|-------------------|
| Mr Martin Holmes (Chair) | APVMA | 3 | 3 |
| Ms Kathy Nolan Mr Geoff McAlpine | ACCORD Australia | 3 3 | 2 2 |
| Mr Kim Baker Mr Philip Fleming | Aerosol Association of Australia | 3 | 0 2 |
| Mr Michael HR Hambrook | Australian Paint Manufacturers’ Federation | 3 | 0 |
| Dr John McCaffrey | Australian Racing Board | 3 | 2 |
| Dr Finola McConaghy Dr Keren Cox-Witton | Australian Veterinarians in Industry | 3 | 2 1 |
| Dr Bill Darmody Dr Finola McConaghy | Australian Veterinary Association | 3 | 0 1 |
| Dr Peter Holdsworth | Animal Health Alliance (Australia) Ltd | 3 | 2 |
| Dr Adrian Harris | CropLife | 3 | 3 |
| Mr Kevin Bodnaruk | Horticulture Australia Limited | 3 | 3 |
| Ms Utte Assenmacher | Pet Food Industry Association of Australia | 3 | 2 |
| Ms Stephanie Leach Ms Melita Shalders | Plastics and Chemicals Industries Association | 3 | 2 1 |
| Two of: Mr Ian Saunders Mr Mark Albrecht Mr Neil Sammons Mr Robert Schufft Mr Jim Adams Ms Ruth Davis | The Veterinary Manufacturers and Distributors Association/ Pet Industry Association of Australia | 3 | 3 |

Secretary: Thea Reiman, Telephone 02 6210 4726

Manufacturers' Licensing Scheme Industry Liaison Committee

Purpose

The Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) was established to provide a forum for the APVMA to discuss strategic and operational issues related to the Manufacturers' Licensing Scheme (MLS) for manufacturers of veterinary medicines with industry representatives and auditors. The committee met four times in August and November 2006 and in February and April 2007.

Terms of reference

The committee was created to promote active engagement of key stakeholders by:

- obtaining the views of industry members and auditors on issues of an operational, technical or strategic nature
- advancing the development and review of operating procedures, manufacturing standards and guidelines relevant to the MLS
- providing industry input into APVMA operational planning processes related to manufacturing issues
- identifying opportunities for regulatory reform within the existing framework
- considering the impact of proposed policy changes on APVMA operations and implications for industry
- facilitating communication with industry and other stakeholders.

Highlights

The implementation of the new Veterinary Chemical Products (Manufacturing Principles) and the Australian Code of Good Manufacturing Practice for Veterinary Medicines, dominated the activities of the committee during the past year. In particular, the committee considered changes to the audit report forms and checklists that would be used to enforce compliance to the new manufacturing standards.

Additional issues considered during 2006–07 included:

- changes in the regulatory environment for chemicals
- progress with auditing and licensing of veterinary medicine manufacturers
- feedback from manufacturers on the audit process
- streamlining the audit processes
- auditing priorities for 2007–08
- various GMP issues, including retrospective validation and veterinary devices
- the Auditors' Workshop
- industry seminars
- progress with the Overseas GMP Scheme
- operation and management of mutual recognition agreements
- options for cost sharing associated with the audits of foreign manufacturing sites.

Attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings is shown in Table B5.

Table B5: Membership and attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings 2006–07

| Member | Organisation | Meetings eligible to attend | Meetings attended |
|---|--|-----------------------------|-------------------|
| Dr Bruce Johnson (Chair) | APVMA | 4 | 4 |
| Mrs Kathy Winterton | APVMA | 4 | 3 |
| Mr Drew Ward (Secretariat July to December) | APVMA | 4 | 3 |
| Mr Allan Smalley (Secretariat January to June) | APVMA | 2 | 2 |
| Mr Andrew Duncum | Animal Health Alliance (Australia) Ltd | 4 | 4 |
| Dr Peter Holdsworth | Animal Health Alliance (Australia) Ltd | 4 | 2 |
| Mr Ian Wheatley | Auditors' representative | 4 | 4 |
| Mr Bill Blackhall | The Veterinary Manufacturers and Distributors Association | 4 | 4 |

Contact: Dr Bruce Johnson, APVMA, telephone 02 6210 4803



Appendix C: Freedom of Information

Section 8 of the *Freedom of Information Act 1982* (the FOI Act) requires each Australian Government agency subject to the FOI Act to publish detailed information on its organisation, functions and powers and on arrangements for public involvement in the formulation of agency policy or administration of any enactment or scheme. This statement, together with the information contained in this report, is intended to meet the requirements of the FOI Act.

Requests for information under the *Freedom of Information (FOI) Act 2006–07*

The APVMA received 13 requests for information under the FOI Act during 2006–07.

To request access to documents under the FOI Act write (with the associated application fee) to:

FOI Coordinator
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

The power to grant or refuse access to APVMA documents is held by the CEO, each of the program managers and section managers. The CEO and program managers have internal review powers. Initial FOI enquiries may be made by telephoning 02 6210 4785.

Organisation and structure

During the reporting period, the APVMA operated under the direction of a Board of Directors. Further details about the APVMA Board are in Chapter 5, 'The Organisation', and at Appendix A.

The APVMA's premises are situated in Canberra at:

18 Wormald Street
Symonston ACT 2609

Postal address:
PO Box 6182
Kingston ACT 2604

APVMA's functions and powers

The APVMA is responsible for assessing and registering pesticides and veterinary medicines proposed for supply and use in Australia and controls them up to and including the point of retail sale. The APVMA has functions and powers that are conferred upon it by the Administration Act, the Agvet Code and the Agvet Regulations, and by certain state and territory laws.

Functions

The APVMA's functions are to:

- assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products
- provide information to the Australian Government and its agencies and the states and participating territories about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for

such products, and to cooperate with those Australian Government agencies on matters relating to the management and control of chemical products

- keep records and statistics of approvals and registrations it has granted, and permits and licences it has issued under the Agvet Code
- evaluate the effects of the use of chemical products in the states and participating territories
- cooperate with the Australian Government and its agencies and the states and participating territories to facilitate a consistent approach to the assessment and control of chemicals
- in cooperation with the Australian Government and its agencies and the states and participating territories, develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products in the states and participating territories
- collect, interpret, disseminate and publish information relating to chemical products and their use
- encourage and facilitate the application and use of results of evaluation and testing of chemical products
- exchange information relating to chemical products and their use with overseas and international bodies having functions similar to those of the APVMA
- when requested by the Minister, or on its own initiative, report to or advise the Minister on any matter relating to chemical products or arising in the course of the performance of its functions
- encourage and facilitate the introduction of uniform national procedures for controlling the use of pesticides and veterinary medicines
- fund and cooperate in a program designed to ensure that active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products comply with the Agvet Code and the Agvet Regulations.

Powers

The APVMA has powers to do all that is necessary or convenient to be done in connection with the performance of its functions, which may include:

- entering into contracts
- acquiring, holding and disposing of real and personal property
- occupying, using and controlling any land or building owned or held under lease by the Commonwealth of Australia, a state or a territory and made available for the purposes of the APVMA
- making available to the public, either without charge or upon payment of a fee to the APVMA, manuals, reports, lists of requirements and other documents
- doing anything incidental to any of its powers.

Ministerial powers

In accordance with section 10 of the Administration Act, the Australian Government Minister responsible for administering agricultural and veterinary chemicals legislation may direct the APVMA in writing in relation to the functions or powers that have been conferred on it under applicable Commonwealth of Australia, state and territory laws. The APVMA must comply with any such direction. During 2006–07, the Minister gave no such direction.

Access to information

Website

Information on the APVMA's structure, functions, powers and publications may be obtained via the APVMA's website at www.apvma.gov.au

Public registers

The APVMA maintains databases to store, manipulate and record product applications, to track submissions, and for product registration details, financial records, mailing lists and other information. Staff details and industry and stakeholder contact details are stored on databases. Access to the following public registers is possible by arrangement, by visiting the APVMA office during business hours, or through the APVMA's website:

- Register of Agricultural and Veterinary Chemical Products, known as the Public Chemicals Registration Information System (PUBCRIS), for information on numbers and approved uses of registered pesticides and veterinary medicines
- Record of Permits
- Record of Approved Active Constituents for Chemical Products.

Files and records

The APVMA maintains files on specific chemicals and on a range of topics relating to its operations and functions. Agreements, protocols, criteria and guidelines on the registration process and the development of technical data are also maintained. The APVMA also retains technical information in the form of individual product applications.

APVMA publications

The APVMA produces publications on the NRS and related matters. These publications include:

- *the APVMA Gazette* (published monthly)
- information sheets
- community briefs
- Corporate Plan and Annual Operational Plan
- Annual Report
- Service Charter
- People Plan
- media releases
- *Manual of Requirements and Guidelines* (MORAG Ag and Vet)

- labelling code of practice
- guidelines for pesticides
- guidelines for veterinary medicines
- guidelines on chemistry and manufacturing aspects
- specific guidelines
- efficacy and safety guidelines
- setting maximum residue limits
- guidelines for recall of agricultural and veterinary chemicals
- review of chemicals
- Code of Good Manufacturing Practice
- reporting adverse experiences with pesticides or veterinary medicines
- agricultural and veterinary public release summaries.

Copies of publications may be obtained by contacting:

Public Affairs Section

Tel: 02 6210 4871

Fax: 02 6210 4874

Email: contact@apvma.gov.au

Confidential information

Some APVMA documents, particularly individual chemical product applications, contain confidential commercial information and may not be divulged by the APVMA except in accordance with the provisions of section 162 of the Agvet Code or released under the FOI Act.

Public consultation

Special consideration is given to the APVMA's consultative mechanisms with the agricultural and veterinary chemicals industry and other relevant specialised industry sectors and community groups. The APVMA has a general policy of making itself accessible to industry associations and community organisations. It consults regularly with a wide range of groups and organisations with relevant interests and maintains close contact with rural and service industries, researchers and other government agencies with an interest in agricultural and veterinary chemicals. For more detail on the APVMA's consultative framework, see Appendix B.

Appendix D: Consultancies

In 2006–07 the APVMA spent a total of \$629 237 (GST inclusive) on consultants, awarding 39 consultancy contracts during that period. The following table lists only those consultancies engaged to the value of \$10 000 or more (including GST) and details the amounts actually paid by the APVMA in the financial year. The reason for engaging the consultancy services was a requirement for specialist expertise not available in the APVMA.

| Consultant | Activity | Amount |
|---------------------------------|---|-----------|
| Australian Government Solicitor | Legal advice | \$10 563 |
| Clayton Utz Lawyers | Legal advice | \$67 733 |
| Creative—Cre8tive | Website design and development | \$51 950 |
| Dimension Data Australia | IT Hardware relocation | \$28 973 |
| Dr James Renwick | Legal advice | \$14 664 |
| Gibson Quai AAS Pty Ltd | Telephony system evaluation | \$14 960 |
| Haddo Pty Ltd | Website management | \$24 850 |
| Hubnet Global Resources Pty Ltd | IT Support | \$29 886 |
| Hugh Watson Consulting | Organisational review | \$49 500 |
| Martin Matisons Consulting | Residue review—Paraquat ECRP | \$30 780 |
| Masters Le Mesurier | Uhrig readiness audit | \$37 950 |
| Michael Griffin Consulting | Advice on compliance conditions | \$11 880 |
| Spectrum Graphics | Graphic design | \$16 458 |
| Smithworks Consulting | Management of Annual Report | \$12 091 |
| Trentora Pty Ltd | IT Support | \$29 565 |
| Wilde & Woollard | Engineering oversight and technical assistance—new Symonston premises | \$27 508 |
| Williams, Love & Nicol Lawyers | Legal advice | \$19 925 |
| Vose Consulting | Critique of scientific paper— Virginiamycin | \$73 808 |
| Total | | \$553 044 |