Australian Government

Australian Pesticides and Veterinary Medicines Authority

Compliance & Monitoring

An overview

Our objective

To enforce the agvet legislation.

How do we do it?

- The APVMA Compliance and Monitoring section is part of the Office of the Chief Regulatory Scientist.
- The team consists of:
  - Adverse Experience Reporting Program (AERP)
  - Compliance and Investigations
  - Hormonal Growth Promotant Program
  - Recalls and Levy Audit.

Adverse Experience Reporting Program

- Post-registration program that assesses reports of adverse experiences associated with the use of a registered veterinary or agricultural chemical product.
- The majority of reports relate to veterinary medicines.
- The APVMA expects that the most comprehensive reports will come directly from veterinary professionals.
- More information is online: apvma.gov.au/node/69.

What is an ‘adverse experience’?

An unintended or unexpected effect on animals, human beings or the environment, or lack of efficacy associated with the use of a registered veterinary (or agricultural) chemical product.

Registration holders have a responsibility to report: See *Agricultural and Veterinary Chemicals Code Act (1994)*

Section 161 - Notification of new information to APVMA

Process

- Triage/assessment
- Investigation, consultation with expert areas
- Classification (causality algorithm)
  - probable/Probable Off-label
  - possible/Possible Off-label
  - unknown
  - unlikely
- Referral (internal expert areas, state regulators, registration holders)
- Monitoring for trends → regulatory action

AERP and veterinary professionals

- Submission of reports or concerns to the APVMA:
  - online reporting form (link here)
  - email (AERP@apvma.gov.au)
  - phone: 1800 700 583.
- Professional advice helps the APVMA to more accurately classify adverse experiences.
- **Vets are on the frontline** – have a working knowledge of product use (safety/efficacy, label deficiencies, etc).
- Help us help you!

Recall notices

- The APVMA may issue recall or stop supply notices when:
  - a product is unregistered or the registration is being re-considered under section 101 of the Agvet Code,
  - the formulation does not meet the safety, trade or efficacy criteria; the concentration, composition or purity differs more than the prescribed extent as outlined in section 102 of the Agvet Code,
  - the label differs from the approved label, (including being unapproved) under section 103 of the Agvet Code,
  - we consider there is a need for our intervention based on risk, noncompliance with Agvet legislation or an absence of responsible product stewardship.

Recalls and veterinary professionals

- Subscribe to receive updates to our recalls website here.
- Monitor products, labels, and adverse experiences.
- Tell us if you see a problem.

Hormonal Growth Promotants

- Some countries including the European Union (EU) require continued assurance from Australia that exported beef and beef products have not been treated with Hormonal Growth Promotants (HGPs).
- The National HGP Monitoring Control System provides this assurance by enabling Australian authorities to account for the importation, supply and use of HGPs. The APVMA plays a significant role in the operation and management of the system by authorizing all suppliers of HGPs and ensuring these suppliers meet their legal obligations in the supply process.
- All importers, manufacturers and suppliers must keep accurate records. The supply of HGPs may be subject to audit by the APVMA.
- You can find more information here.

Compliance

- The team categorise and prioritise allegations or referrals based on risk, resources and priorities.
- Like all regulators we have finite resources and must allocate them to tasks wisely.
- The APVMA appoints Inspectors who can apply for and execute investigation and monitoring warrants, conduct interviews, issue infringement notices and formal warnings and commence civil and criminal prosecutions.
- The APVMA takes a proportionate response to contraventions.
- More information here.

So how much work is in all of this?

AERP stats FY2019–20: 1268 serious (814 classified as 'related to')

	FY2018–19	FY2019–20 (YTD)
Allegations received	200	254
Referred for Prosecution	0	2
Notices to Produce or Attend issued	2	2
Monitoring Warrants	1	0
Investigative Warrants	4	0
Manufacturer-initiated recalls	11	11 (7 vet, 4 ag)
APVMA-initiated recalls	1	18 (15 vet, 3 ag)
Requests to Australian Border Force to apply Customs Act 1901	16	29
Formal warnings issued	4	3
Infringement Notices issued and value	5 issued	2 issued
	4—Landmark ($28,000) 1—Spick N Clean ($5,000)	1—Animal Health Supplies ($26,250) 1—Stotras Pty Ltd ($15,750)
	Total: $33,000	Total: $42,000
Enforceable Directions issued	1	0
Enforceable Undertakings	0	0
Cases closed	212	156

It’s a busy place

- HGP Program stats FY2020:
  - 5 field audits.
  - 1507 monthly verification checks completed.
  - 209 current notification number holders (suppliers).
  - 22 new notification number holders (suppliers).
  - Education component to remind suppliers of their responsibilities and consequences: apvma.gov.au/node/4136.
  - Ongoing monitoring and audit of doses supplied.

Compounding & prescribing rights

Where does the APVMA fit in?

Only when veterinary chemicals are unregistered and are possessed, compounded or prescribed unlawfully in the State or Territory jurisdiction.

Our takeaway messages

- Veterinary professionals have an important role to play in the regulation of registered chemical products.
- The APVMA wants you to know how to:
  - Report problems with a chemical product: apvma.gov.au/node/1101.
  - Report Adverse Experiences: apvma.gov.au/node/311.
  - Report Compliance Issues: apvma.gov.au/node/3841.
  - Receive Recall notices: apvma.gov.au/node/27171.

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