Pharmacovigilance: presentation by a national competent authority [Australia]

Regional Seminar for OIE National Focal Points for Veterinary Products (6th Cycle)

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Australian Pesticides and Veterinary Medicines Authority (APVMA)

• Government **statutory authority** established in 1993

• Centralisation of registration

• Federal regulator for the sale and supply of safe and effective agricultural chemicals and veterinary medicines in Australia.

• Responsibilities outlined under:
  • *Agricultural and Veterinary Chemicals (Administration) Act 1992*
  • *Agricultural and Veterinary Chemicals Code Act 1994.*
Adverse Experience Reporting Program

• Post-registration pharmacovigilance program established in 1995

• Provides a means of facilitating regulatory action that may be necessary to assure the continued safety, quality and effectiveness of registered products

• New streamlined program implemented in 2002
  • Meets international standards
  • Incorporates risk management, evaluation and causality assessments, trend analysis and corrective action

Adverse Experience Reporting Program

- Risk management system
- Contributes to veterinary medicine stewardship
- Aim is to ensure that, when used correctly, veterinary medicines are safe, effective and instructions/warnings on the label is appropriate
Adverse experience

Definition
An unintended or unexpected effect on animals, human beings or the environment, or lack of efficacy associated with the use of a registered veterinary chemical product when used according to label instructions.
Adverse experience

Serious adverse experience
Any adverse experience that results in death, is life-threatening, results in persistent or significant disability or incapacity, prolonged duration of serious signs or is a congenital abnormality or birth defect in animals. A serious adverse experience in humans is one that requires medical treatment or involves death.
Examples of “serious”

Humans
• death
• medical treatment required.

Cattle, sheep and pigs
• death
• more than one veterinary visit
• more than 10 per cent morbidity
• welfare implications.

Horses
• death
• hospitalisation or more than one veterinary visit
• welfare implications.

Poultry
• more than five per cent increase in base mortality
• more than 10 per cent morbidity
• welfare implications.

Small animals
• death
• hospitalisation
• welfare implications.
How an adverse experience report is processed by the APVMA
How an adverse experience report is processed by the APVMA
Ensuring the safety of AgVet products

Welcome to the Adverse Experience Reporting Program

The APVMA evaluates all the adverse experience reports it receives involving registered agricultural and veterinary chemical products in Australia.

What is an adverse experience?

An adverse experience is an unintended or unexpected outcome associated with the registered use of a product when used according to the approved label instructions. This includes impacts on human beings, animals, crops and the environment or a lack of efficacy.

How do I lodge an adverse experience report?

You can submit a report online by selecting the "Start a report" option below. Please complete all the required fields(*) and provide as much detail as possible (including details of vets, doctors and/or agronomists reports, pathology and post mortem reports etc., where appropriate). Please note that the information you supply should be accurate and correct. Partially completed reports can be saved and resumed at a later time by selecting the "Resume report" button below.

Once you have completed the form, the APVMA will provide a reference number for you to record and quote in any further correspondence about your report.

View our privacy policy and
Start a report

Continue a partially completed report
Resume report
Reporting

Risk analysis

Low risk - adverse reactions that have not occurred previously, involve only minor animal reactions or are not of public interest.

Medium risk

High risk
Reporting

Risk analysis

Low risk

Medium risk - reports include human reactions that do not require medical attention and are not widespread, non-serious reactions in animals, and possible matters of high public interest.

High risk
Reporting

**Risk analysis**

Low risk

Medium risk

**High risk** - High-risk reports include those involving reactions in humans that require medical attention, serious reactions in animals and matters of high public interest.
How an adverse experience report is processed by the APVMA
Reporting

Classification of reports

Probable - where the APVMA is satisfied that the adverse experience, whether expected or not, was related to the use of the product.

Possible - where the APVMA is not satisfied that the adverse experience was related to the use of the product, but the possibility that the product was related cannot be excluded.

Unlikely - where the APVMA is satisfied that the adverse experience was not related to the use of the product.

Unknown - where there is insufficient information to allow classification or where reliable data is unavailable.
Reporting

Trend analysis
Reports deemed ‘Probable’ or ‘possible’ are further analysed.

\[
\text{Reporting incidence} = \frac{\text{Number of adverse experience reports}}{\text{Number of doses sold}}
\]

Signal detection is when information is received suggesting a causal association or change in causal association between the use of a product and a related event, and where it is assessed to be of sufficient likelihood to justify investigation of the situation.

Control limit (where further action may need to be taken) is one or more per 100 000 doses sold.

Determination of action
Reporting – transparency

- The AERP receives approximately 7,000 reports of adverse events each year.
- A summary of adverse experience reports (AERs) is published on data.gov.
- The publishing of this data fulfils the reporting requirements for the agency as is prescribed in the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995*. The APVMA website has historical reports.
## Reporting – transparency (data.gov)

<table>
<thead>
<tr>
<th>Financial Year (FY)</th>
<th>Total Number of Reports Received</th>
<th>Total Number of Duplicate, Unrelated, and Nonserious Reports</th>
<th>Total Number of Serious Incidences Related To Registered Products</th>
<th>Serious Incidences Classified as Related To</th>
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<td></td>
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Corrective Actions?
Stakeholder engagement: a critical component of pharmacovigilance programs...

- Education of practicing veterinary practitioners regarding the functions of the APVMA, their role as a clinician in the reporting of adverse experiences, and the broader-scale importance of pharmacovigilance in Australia.

- Facilitating the reporting of adverse experience reports through educational initiatives and the provision of information to producers, the public, and other industry stakeholders.

- Working across the APVMA and with industry stakeholders to consider emerging issues such as antimicrobial resistance. Such areas include consideration of the availability and use of antibiotic substances in Australia, the reporting of adverse experiences involving these chemical products, and the level of risk that such issues pose.
Questions?

Sampling Malaysian chickens in Australia – Christmas Island Survey 2017……