



Australian Government  
Department of Agriculture

# Pharmacovigilance: presentation by a national competent authority [Australia]

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

Dan Edson

14-16 January 2020

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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.*



## **Australian Government**

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## **Australian Pesticides and Veterinary Medicines Authority**

# 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

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## The veterinary pharmacovigilance program of the APVMA

P LINNETT and P DAGG

Australian Pesticides & Veterinary Medicines Authority, Adverse Experience Reporting Program, John Curtin House, 22 Brisbane Avenue, Barton, Australian Capital Territory 2604

This paper provides an overview of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) Adverse Experience Reporting Program for veterinary medicines (AERP Vet). It outlines the history of the AERP Vet and how the program investigates adverse experience reports received from veterinarians, product registrants and members of the public. The benefits to veterinarians of such a program are highlighted and include the ability to trust in the safety, quality and efficacy of the veterinary drugs that they handle and administer daily. *Aust Vet J* 2005;83:32-37

|          |   |
|----------|---|
| AERP     | Adverse Experience Reporting Program                          |
| AERP Vet | Adverse Experience Reporting Program for veterinary medicines |
| APVMA    | Australian Pesticides and Veterinary Medicines Authority      |
| AVA      | Australian Veterinary Association                             |
| IVS      | Australian IVS Annual   |

assessments of adverse experience reports, trend analysis and corrective action determinations. The AERP Vet is audited annually as part of the quality system that operates at the APVMA to ensure that the requirements of the International Organisation for Standardisation are met.

The aim of the AERP Vet is to ensure that, when used correctly, veterinary medicines are safe, effective, of acceptable quality, and that the instructions and warnings on the labels are appropriate. It is a quality assurance program that helps facilitate responsible management by all parties concerned (namely the product registrants,<sup>3</sup> users of the products, the APVMA and the State and Territory authorities) of veterinary medicines throughout their lifecycle. The AERP Vet completes the feedback loop around risk management, which begins with registration, and contributes to stewardship of veterinary medicines throughout their lifecycle by:

- providing timely triggers and better informed decision-making relating to changes to safety measures for the storage and use of the products

Linnett and Dagg 2005. The veterinary pharmacovigilance program of the APVMA. *Australian Veterinary Journal*: **83 (1-2)**: 32 - 37

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# 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

The screenshot shows the official website of the Australian Government Australian Pesticides and Veterinary Medicines Authority. The page is titled "Adverse Experience Reporting Program" and is part of the "Compliance and Enforcement" section. The header includes the Australian Government logo and navigation links: ABOUT, ONLINE SERVICES, NEWS AND PUBLICATIONS, and CONTACT US. A search bar is also present. The main navigation bar highlights "COMPLIANCE AND ENFORCEMENT". The page content includes a sidebar with links to "The importance of the AERP", "Scope of the AERP", "Who can report an adverse experience?", and "Adverse Experience Reporting Program for veterinary medicines". The main text describes the AERP as a post-registration program that assesses reports of adverse experiences associated with the use of a registered veterinary medicine or agricultural chemical. It states that it is vital to record, assess and classify adverse experiences to detect uncommon events not evident during the initial registration process of a product. The program provides a means of facilitating regulatory action that may be necessary to assure the continued safety, quality and effectiveness of registered products. It also mentions that anyone can report an adverse experience to the AERP, for example—farmers, pet owners, gardeners, veterinarians or the general public.

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HOME REGISTRATIONS AND PERMITS CHEMICALS AND PRODUCTS COMPLIANCE AND ENFORCEMENT OUR SCIENCE

Compliance and Enforcement

Adverse Experience Reporting Program

The importance of the AERP

Scope of the AERP

Who can report an adverse experience?

Adverse Experience Reporting Program for veterinary medicines

Home ► Compliance and Enforcement ► Adverse Experience Reporting Program

## Adverse Experience Reporting Program

The Adverse Experience Reporting Program (AERP) is a post-registration program that assesses reports of adverse experiences associated with the use of a registered veterinary medicine or agricultural chemical.

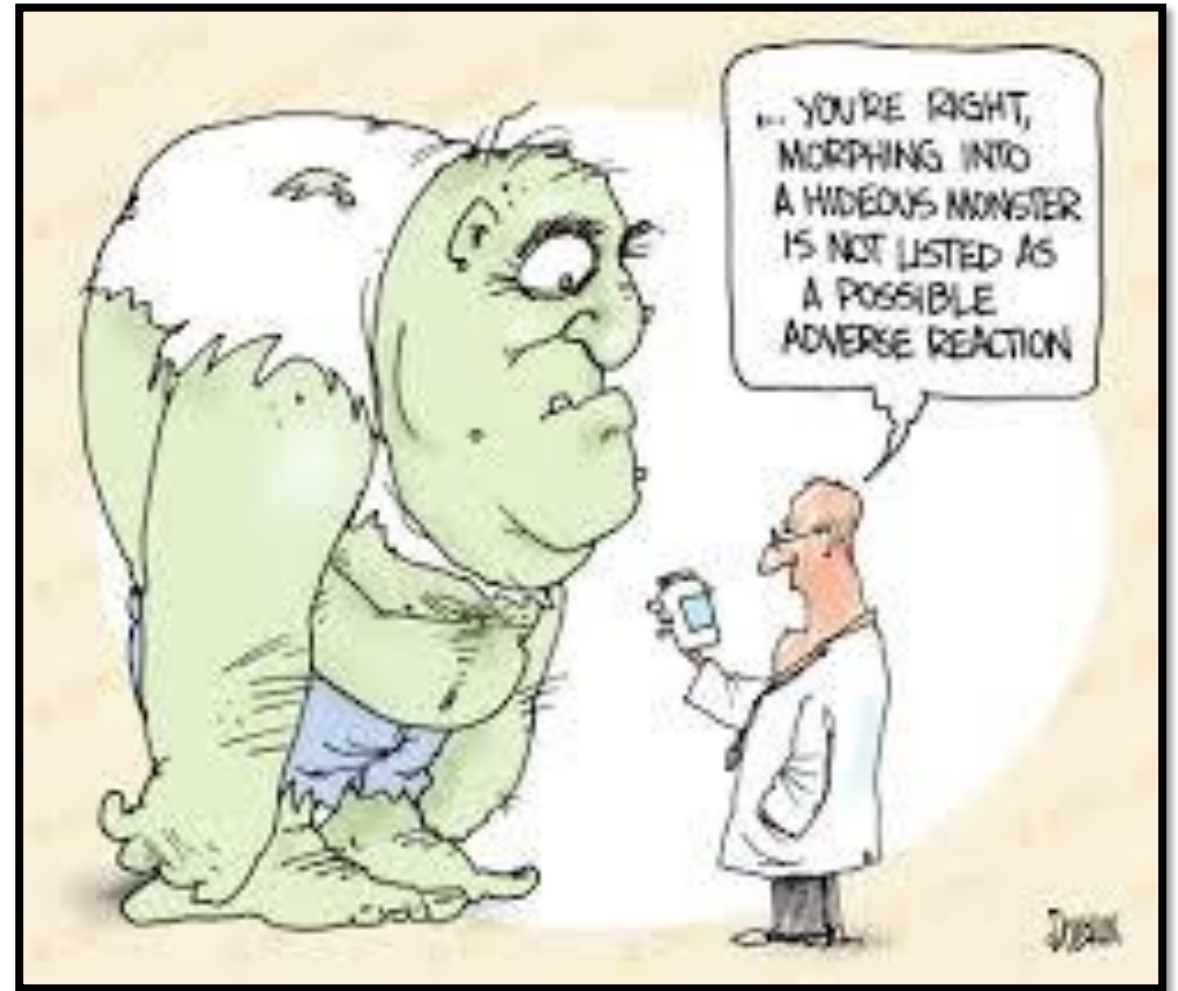
It is vital to record, assess and classify adverse experiences to detect uncommon events not evident during the initial registration process of a product. The program provides a means of facilitating regulatory action that may be necessary to assure the continued safety, quality and effectiveness of registered products.

Anyone can report an adverse experience to the AERP, for example—farmers, pet owners, gardeners, veterinarians or the general public.

# 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.

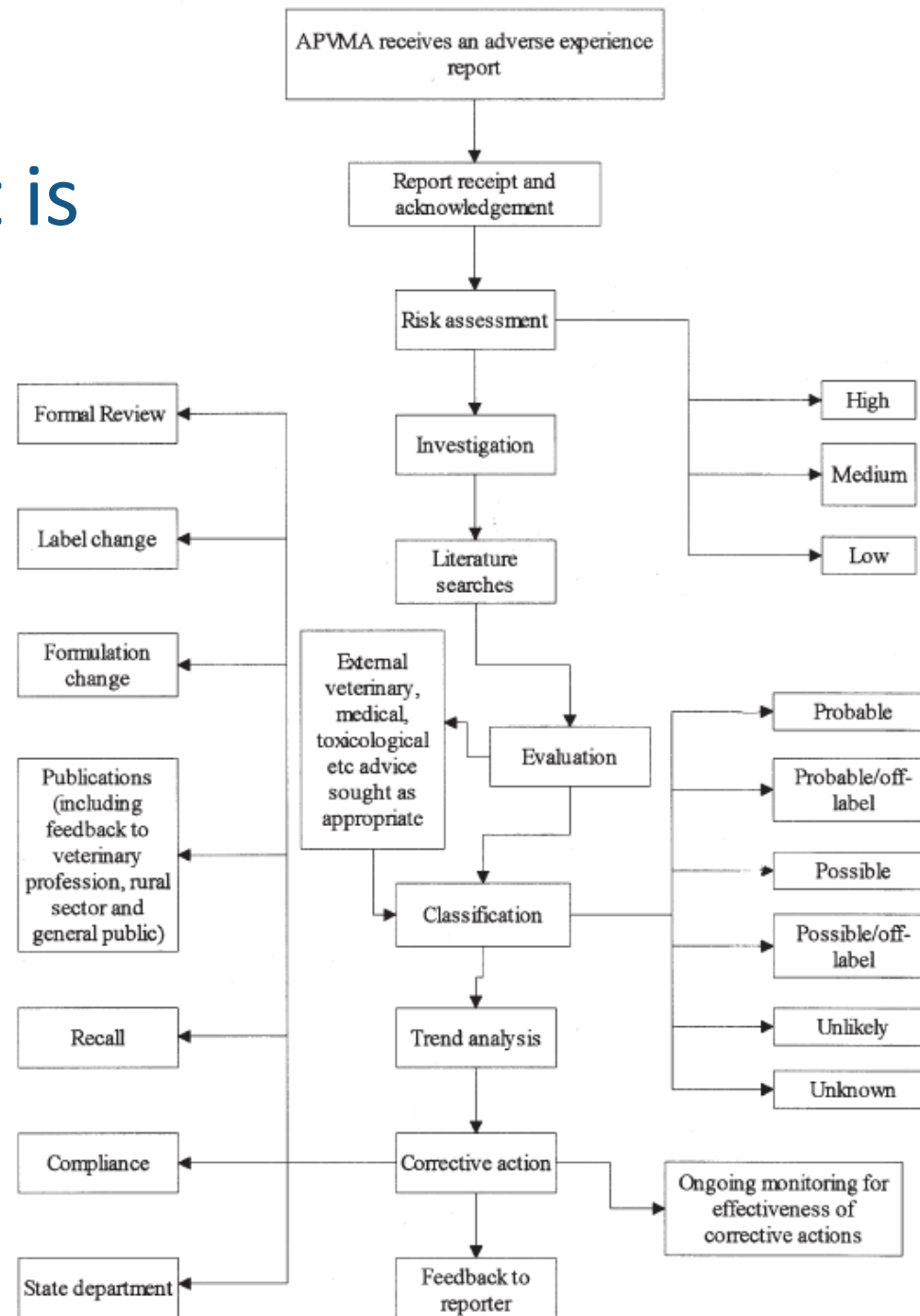
### Poultry

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

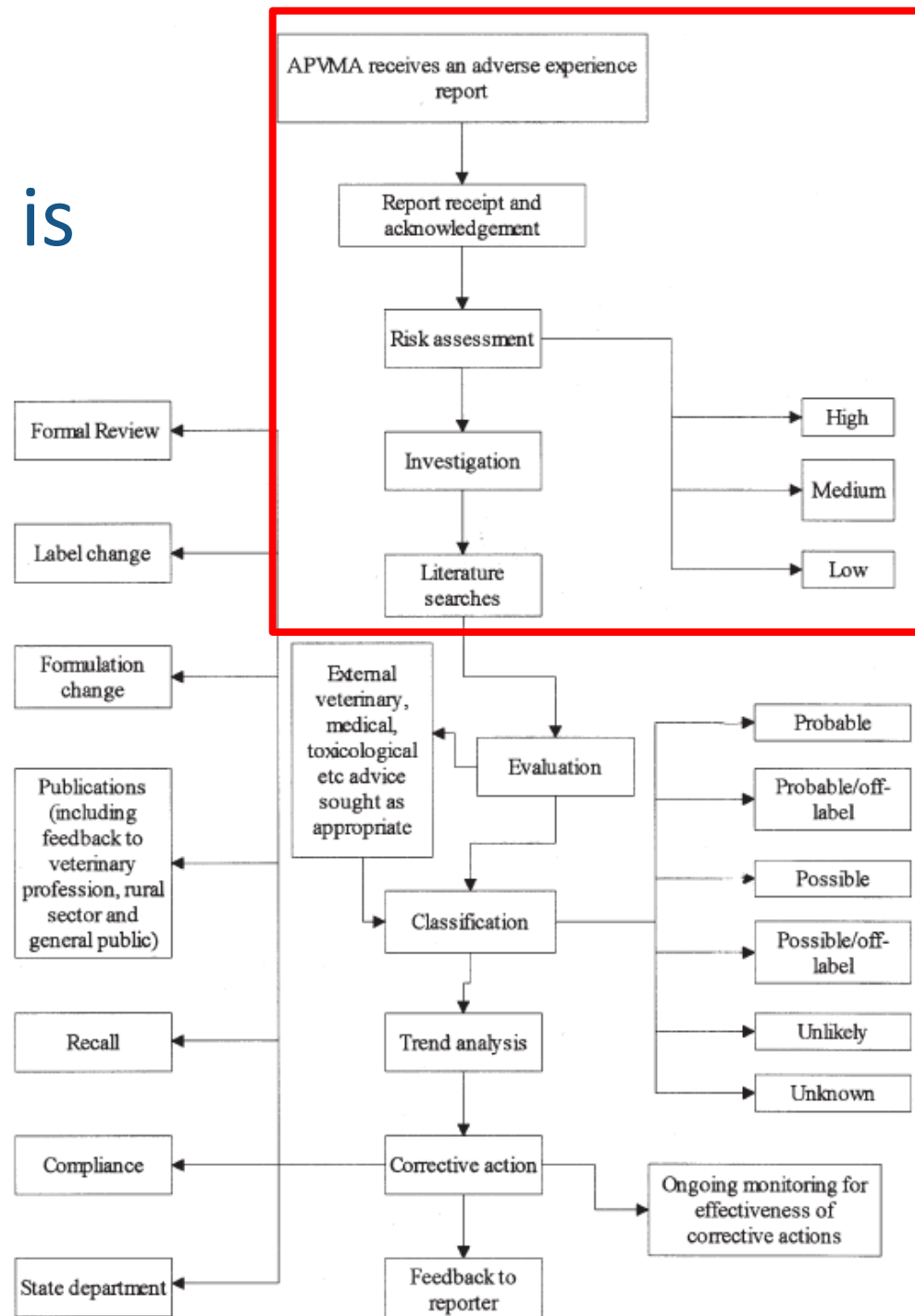
### Small animals

- 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



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Veterinary Medicines Authority

## Adverse Experience Reporting Program

HomeProduct searchPermit search**Chemical problem reporting**Registration and permitsFeedbackHelp

**Notes:**

- If you can't see the form below, please use [this link](#) to submit a report.
- At the product details step, if you don't know the product name, or you cannot find it using the search button, please just tick the 'Unknown or unregistered product?' box and enter any identifying details.

### 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



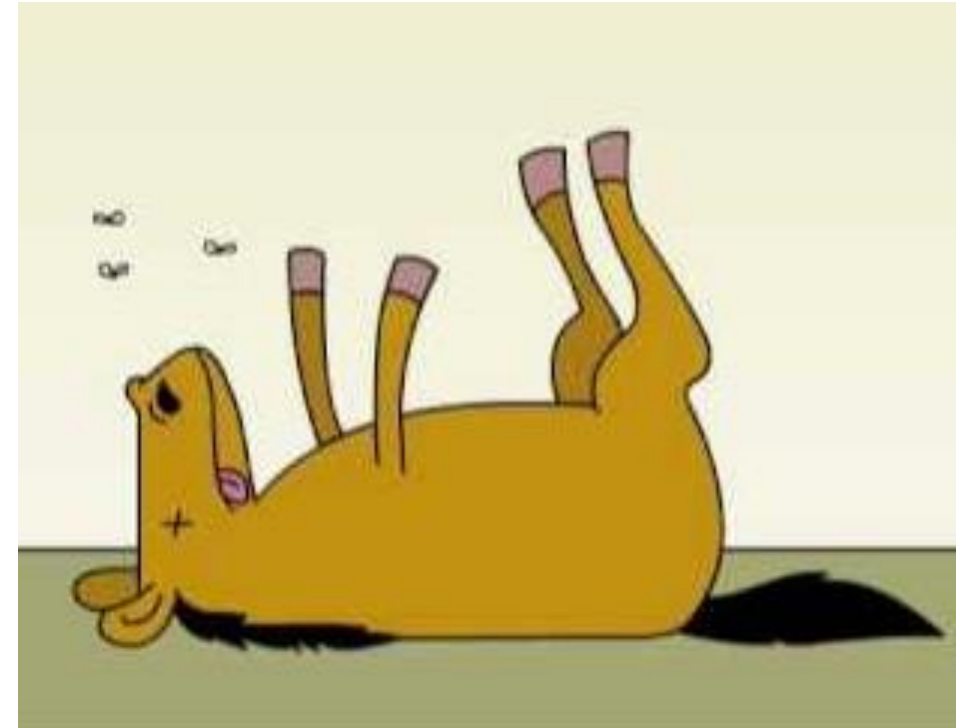
# Reporting

## Risk analysis

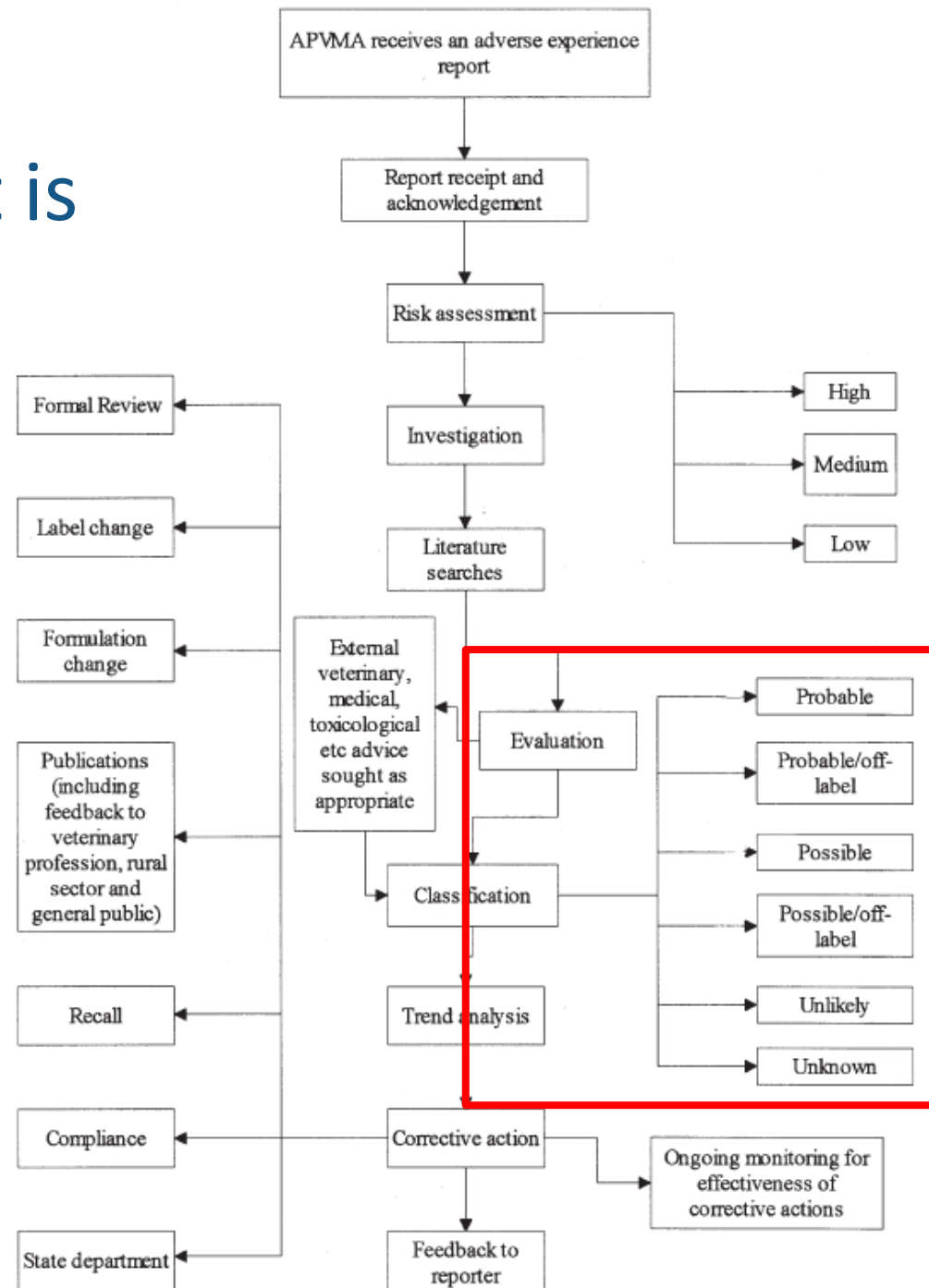
Low risk

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



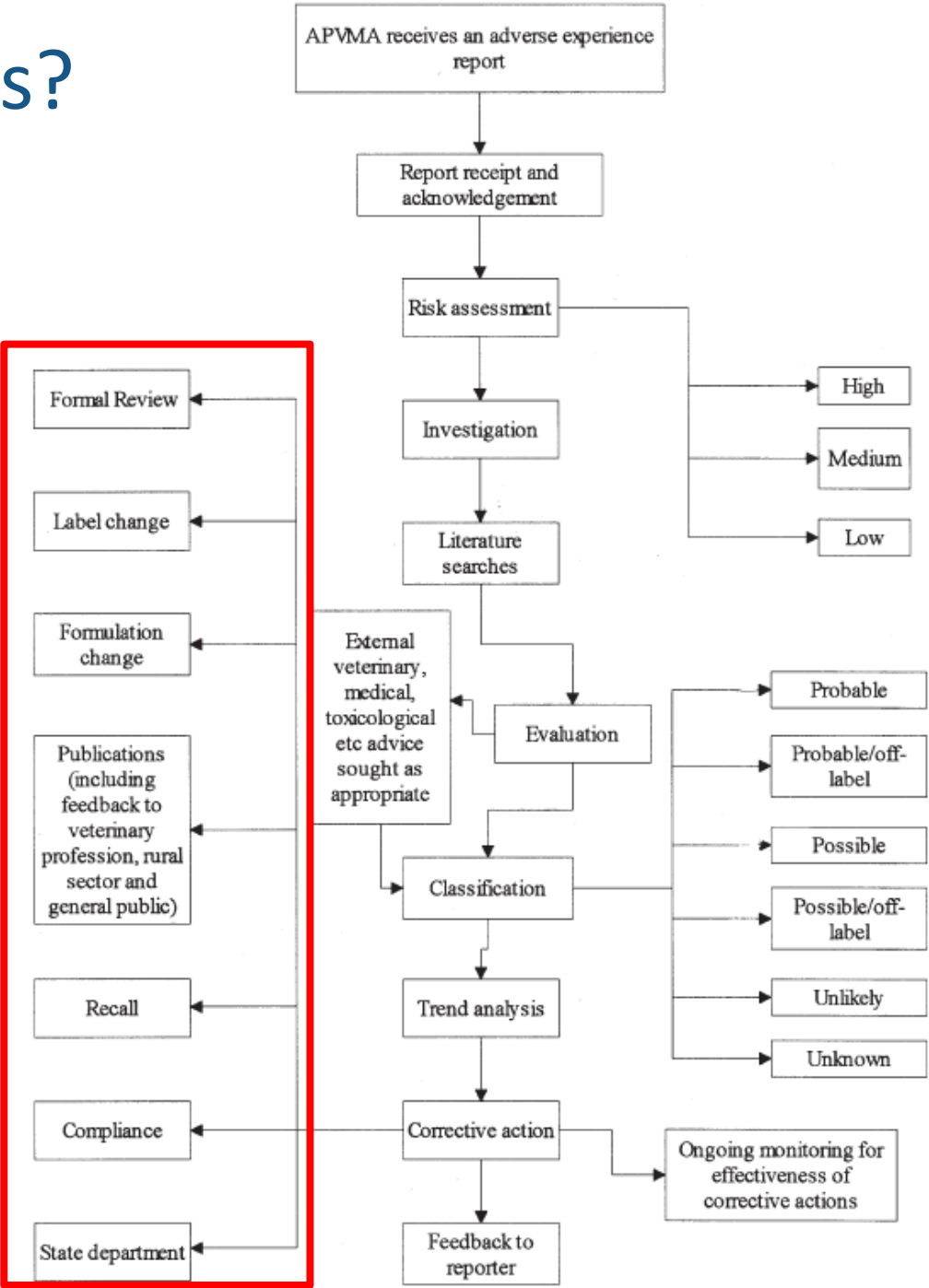
# Reporting – transparency

- The AERP receives approximately 7,000 reports of adverse events each year.
- A summary of adverse experience reports (AERs) is published on [data.gov](https://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)

| Financial Year (FY) | Total Number of Reports Received | Total Number of Duplicate, Unrelated, and Nonserious Reports | Total Number of Serious Incidences Related To Registered Products | Serious Incidences Classified as Related To |             |          |             |       |
|---------------------|----------------------------------|--|---|---|-------------|----------|-------------|-------|
|                     |                                  |  |   | Animal Health                               | Crop Health | Efficacy | Environment | Human |
| 2015-16             | 3924                             | 3208   | 716   | 469   | 8           | 172      | 5           | 62    |
| 2016-17             | 5229                             | 4373   | 856   | 521   | 44          | 222      | 4           | 65    |
| 2017-18             | 4773                             | 3636   | 1137  | 880   | 10          | 177      | 1           | 69    |
| 2018-19             | 7285                             | 6334   | 951   | 590   | 8           | 238      | 23          | 92    |

# 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.....