Veterinary Pharmacovigilance in the UK: Suspected Adverse Reaction Surveillance Scheme

ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

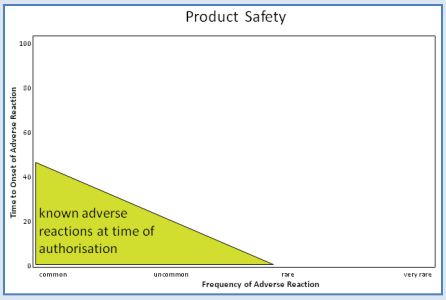
Department for Environment Food and Rural Affairs

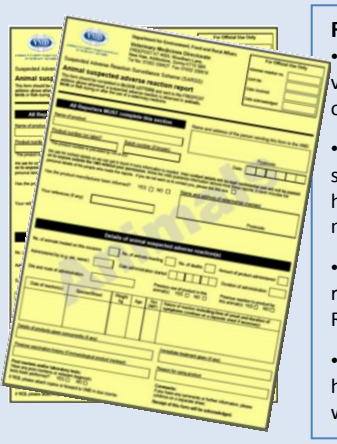
Background

• Pharmacovigilance is the science or activities relating to the detection, assessment, understanding and prevention of adverse events relating to medicines.

• Adverse events are any observation in animals or humans, whether or not considered to be product-related, which is unfavourable or unintended and which occurs after the use of, or exposure to, a veterinary medicinal product.

• The Suspected Adverse Reaction Surveillance Scheme (SARSS) is a national surveillance scheme run by the Veterinary Medicines Directorate to record reports of suspected adverse reactions to veterinary medicines.





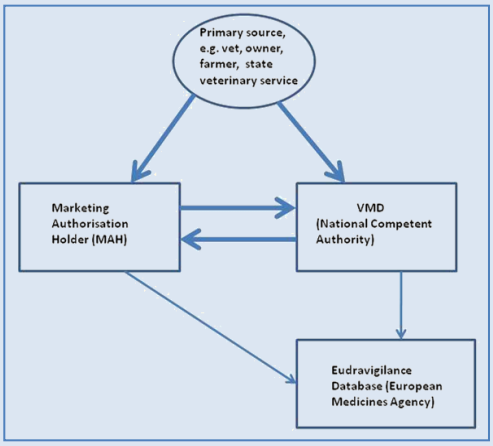
Reporting

• SARSS receives reports from marketing authorisation holders, veterinary practices, farmers, state veterinary services and pet owners.

• All reports are treated in the same way including those reporting suspected lack of efficacy, use of human medicines in animals, human reactions to veterinary medicines, antibiotic residues in milk, meat or eggs and environmental reports.

• Data is entered into a national database and clinical signs reported are coded using the Veterinary Dictionary for Drug Related Affairs (VeDDRA).

• Reports are received electronically from marketing authorisation holders. Vets and owners can report online through the VMD website or using a paper form.



Data analysis

• Manual case-by-case assessments are carried out on all reports received.

• Automated methods have only recently been introduced, based on the statistical analysis of the data.

• In the field of human pharmacovigilance, there is the option of using reference datasets for denominator data, but these datasets are not available in the veterinary field.

• Therefore measures of disproportionality are used to detect statistically significant VeDDRA-drug combinations.

• The use of the Proportional Reporting Ratio (PRR) is currently being implemented. Other potential automated methods include Multi-item Gamma Poisson Shrinker (MGPS), Bayesian Confidence Propagation Neural Network (BCPNN), Reporting Odds Ratio (ROR) and Chi-square test (χ^2).

• Statistically significant signals are then investigated in further detail.

	Cases reporting clinical sign (VeDDRA term)	Cases not reporting clinical sign (VeDDRA term)
Reports involving product	A	B
All other reports	C	D

$$PRR = \frac{A/(A+B)}{C/(C+D)}$$

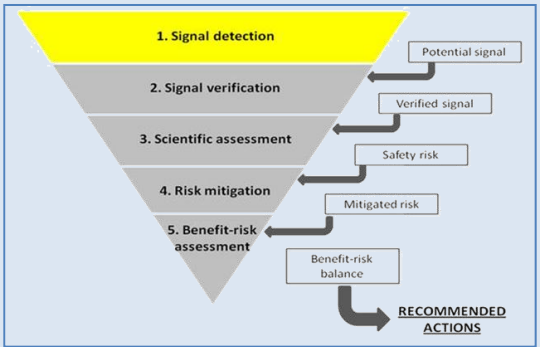
UK National Database

• There are 1,950 VeDDRA terms in the dictionary.

• There are currently approximately 2,200 authorised veterinary medicinal products in the UK.

• The UK National database currently holds data on 34,749 product-VeDDRA combinations.

• Data will be analysed at regular intervals and only new signals will be investigated unless concerns are raised regarding a particular product or adverse event.



Advantages and disadvantages of analysis of data using PRR.

•*Advantages*:

- Relatively easy to implement and understand.
- Provides a system which enables a consistent approach and an audit trail for the detection of new signals.
-Previous system relied on manual detection of signals and therefore the personal experience of the assessor involved.

•*Disadvantages*:

- PRR is only a measure of disproportionate reporting and is not a direct indication of differences of occurrence.
- PRR currently analyses the data on the number of reports and not the number of animals affected (some reports involve multiple animals).

Actions that can be taken following verification and assessment of a new signal:

• Monitoring of future reports for the product.

• Addition of warnings to the packaging and Summary of Product Characteristics (SPC).

• Changes in the authorised use of the product.

• Product or batch recall.

• Suspension of the product from the market until the safety issues are resolved.

• Withdrawal of the authorisation to manufacture the product.

PLEASE REPORT ALL SUSPECTED ADVERSE REACTIONS INCLUDING SUSPECTED LACK OF EFFICACY.

For further information please contact: Suspected Adverse Reaction Surveillance Scheme, Veterinary Medicines Directorate, Tel: 01932 338427, www.vmd.defra.gov.uk