The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food & Rural Affairs.

What happens to reports of adverse events?

All reports received by the VMD are recorded on a database. Every report is acknowledged. Further information, such as post mortem reports or laboratory results, may be requested if they would assist in determining the causal relationship between the product and the reported adverse event. The details of each report are assessed and all suspected adverse events are reviewed regularly by a group of veterinarians, immunologists, pharmacists, toxicologists and ecotoxicologists from the VMD. In addition, all serious adverse events are considered on a regular basis by the Veterinary Products Committee (VPC), a group of independent experts. Adverse reactions in humans are reviewed by the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines, which is a sub-committee of the VPC. VMD representatives also participate in the activities of the European Pharmacovigilance Working Party which meets regularly to monitor and harmonise adverse event reporting in the EU.

Single reports will not usually result in action by the VMD. However, should a pattern of adverse events for a specific product emerge, regulatory actions to improve the safety of that product will be initiated depending on the seriousness of the adverse events and the conditions under which they occurred. Such actions include:

- Addition of warnings to the label of the product.
- 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.
- Suspension of the right to manufacture the product.

What are the benefits of pharmacovigilance?

A good pharmacovigilance system enables the detection of new adverse events. Information derived from pharmacovigilance can also add to our knowledge about possible negative effects of drugs in animals. The reporting of adverse events provides the basis for optimal benefit/risk assessment and thus contributes to the safe use of veterinary medicines.

Veterinarians are provided with feedback on adverse events through the SARSS Report which is published annually in The Veterinary Record. Particular hazards detected through pharmacovigilance are also published in the relevant press. Information on current product or batch recalls is published on the VMD website.

Further information

The VMD website at www.vmd.gov.uk contains information about all aspects of the VMD’s work. The VMD issues a series of Veterinary Medicines Guidance Notes. These guidance notes provide further detail in connection with all aspects of the VMD’s work. They are available on the VMD website at www.vmd.gov.uk/General/VMR/vmgn.htm.

There are further leaflets available in this series which are also available on the VMD website. These cover areas such as:

- The work of the VMD.
- Availability of veterinary medicines.

You can also phone the VMD on 01932 336911 for any additional assistance about veterinary medicines.
What is an adverse event?

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

What is pharmacovigilance?

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem are known as pharmacovigilance. Veterinary pharmacovigilance concerns the safety of veterinary medicines used for the treatment, prevention or diagnosis of disease in animals. The objective is to ensure:

- The safe and effective use of veterinary medicines in animals.
- The safety of people who come into contact with veterinary medicines.
- The safety of veterinary medicines for the environment.

Which adverse events are included in the scope of pharmacovigilance?

Veterinary pharmacovigilance covers all adverse events in animals associated with veterinary medicines. These include:

- Adverse reactions in animals which occur after use in accordance with the advice on the label or following off-label use.
- Suspected lack of expected efficacy after use in accordance with the label.

Adverse reactions in humans following exposure to a veterinary medicinal product or to a treated animal are within the scope of pharmacovigilance.

Two further situations are included in the scope of pharmacovigilance. These are:

- Adverse effects in animals of non-target species, humans or plants through exposure to a veterinary medicine present in the environment.
- Levels of residues of veterinary medicines in tissues or food products of treated food producing animals, that are above the maximum residue limits when the recommended withdrawal period of the given veterinary medicine has been respected.

Which products does pharmacovigilance cover?

In addition to all veterinary medicinal products authorised in the UK, veterinary pharmacovigilance extends to cover adverse events involving non-UK authorised veterinary medicines imported under one of the Veterinary Medicines Directorate (VMD) import schemes, human medicines used in animals under the prescribing cascade, products used in small pet animals under the Small Animal Exemption Scheme and unauthorised products.

Why is pharmacovigilance important?

A well-defined benefit/risk relationship is an integral part of the decision-making process in medicinal therapy. The authorisation of veterinary medicines is preceded by thorough pharmacological and toxicological investigations to ensure that products are safe and effective for the target species. However, only a limited number of animals can be treated in the studies prior to the approval of new products. Adverse events which occur rarely or are specific to certain breeds or groups of animals become apparent only after the medicines have been widely used in clinical veterinary therapy. It is therefore essential that all suspected adverse events are brought to the attention of the VMD.

Who is responsible for pharmacovigilance?

The Suspected Adverse Reaction Surveillance Scheme (SARSS) undertakes veterinary pharmacovigilance in the UK. The scheme is run by a team of specialists at the VMD. The team records, collates and evaluates reports of suspected adverse events submitted to the VMD. All reports are treated in the same way, including those associated with suspected lack of efficacy, off-label use, the use of human medicines in animals, human reactions to veterinary medicines, antibiotic residues in milk, meat or eggs, and environmental problems.

Veterinary surgeons and veterinary nurses are in a unique position to observe adverse reactions and have a key role in the reporting system. While the reporting of suspected adverse events is voluntary, the Royal College of Veterinary Surgeons considers it to be part of a veterinary surgeon’s professional responsibility to the general public. Pharmacists and Suitably Qualified Persons (SQPs) should also record and report adverse events. Animal owners have an important role to play and reports from this source are encouraged. Suspected adverse events can be reported to the marketing authorisation holder of a veterinary medicine, or to the VMD. The marketing authorisation holder has a legal obligation to report serious adverse events involving death or prolonged severe clinical signs to the VMD within 15 days following receipt of the information. In addition, the marketing authorisation holder must report all suspected adverse events in Periodic Safety Update Reports submitted to the VMD at specified intervals.

How can I report an adverse event?

Adverse events should be reported on a Yellow Form. Advice on how to report an adverse event, including Yellow Forms, can be found on the VMD website www.vmd.gov.uk/General/Adverse/adverse.htm. Yellow Forms can also be requested from the following address:

Veterinary Medicines Directorate
FREEPOST KT4503
Woodham Lane
New Haw
Addlestone
Surrey KT15 3BR
Alternatively contact the VMD on 01932 338427 or sarss@vmd.defra.gsi.gov.uk