

How are reports involving people assessed?

After they have been assessed, all reports of side effects in people are reviewed by the Appraisal Panel for Suspected Adverse Reactions to Veterinary Medicines. This is a panel of independent experts supported by specialists from the Department of Health, the HSE and the VMD. Its aims are:

- To evaluate all harmful side effects in humans exposed to veterinary medicines.
- To identify any trends or signs of emerging problems.
- To report its findings to the Veterinary Products Committee (VPC) (an independent committee of experts which advises government Ministers on the safety, quality and efficacy of veterinary medicines).

What follow-up action can the VMD take?

There are a number of possible follow-up actions that can be taken, including:

- Monitoring future reports about the product.
- Recommending that changes are made to the product literature, labels and package leaflets, for example to include appropriate warnings.
- Suspending the sale and supply of the product or of a specific batch of that product.
- Revoking the Marketing Authorisation for the product.
- Suspending the right to manufacture the product.

How can I report a harmful side effect?

If you consider that you or your animal(s) have reacted badly to a veterinary medicine and you need veterinary or medical advice, you should first contact your veterinary surgeon or doctor who will be able to discuss the reaction with you, initiate any treatment required and, where appropriate, report to the VMD. If possible take the medicine container, or label for a large pack, or package leaflet with you.



If you would prefer to report the side effect directly to the VMD you can obtain a yellow report form (MLA252A) from the address below. You may also be able to obtain forms from the person who supplied you with the veterinary medicine. There are also separate forms for reporting environmental incidents and suspected residues of antibiotics in milk.

What can I report?

It is important that ALL harmful side effects to veterinary medicines are reported to the VMD so that appropriate action can be taken to avoid any further harm to animals or people.

Where can I get forms and further information?

For further information or reporting forms please contact:

The Suspected Adverse Reaction Surveillance Scheme
Freepost KT4503
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3BR

Telephone: 01932 338427
Fax: 01932 336618
Web: www.vmd.gov.uk



ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES



Pharmacovigilance



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

What is pharmacovigilance?

The activities relating to the detection, assessment, understanding and prevention of adverse reactions 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.

What is an adverse reaction?

An adverse reaction is a harmful and unintended reaction which is due to exposure to a veterinary medicine administered to an animal at its normal dose. In other words it is any harmful side effect to a veterinary medicine. Adverse reactions can occur in animals treated with veterinary medicines, or in people who are exposed to veterinary medicines or treated animals.

What is the Suspected Adverse Reaction Surveillance Scheme?

The Suspected Adverse Reaction Surveillance Scheme (SARSS) is a voluntary scheme for monitoring reports of suspected adverse reactions to veterinary medicines throughout the UK. The scheme is run by the Veterinary Medicines Directorate (VMD), an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). The scheme records and monitors reactions to veterinary medicines in both animals and people. Adverse reactions in overdose situations are also recorded.

Is anything else recorded?

Yes. The SARSS also records reports of instances where a veterinary medicine does not work as intended (lack of efficacy), adverse environmental effects and problems with residues of veterinary medicines in human food.

How can exposure to a veterinary medicine occur?

Exposure occurs when animals are being treated with veterinary medicines such as vaccines, antibiotics, anaesthetics, tick and flea control products or sheep dips. Exposure to veterinary medicines can occur in people (e.g. when giving tablets or injections, by accidental self-injection, or, when handling recently treated animals).

Which animals are covered by pharmacovigilance?

Pharmacovigilance covers all species of animals treated with veterinary medicines. These include animals kept on farms, in zoos, pets and other animals such as reptiles, wild birds, fish and bees.

What should I do if I notice a harmful side effect?

Harmful side effects to veterinary medicines are rare but if you suspect that one has occurred in an animal, or a person, you should:

- Contact your veterinary surgeon, if your pet is affected, so that it can be treated.
- Contact your doctor for advice and treatment if you are affected.
- Report the reaction to the VMD (see back page for contact details) unless your veterinary surgeon or doctor intends to do so, or report the reaction to the retailer if this is how you obtained the product.

Who can report a harmful side effect and how?

Anyone can report to the VMD an adverse reaction to a veterinary medicine which they have experienced or observed. Members of the public, veterinary surgeons, farmers, doctors, pharmacists, etc. are all encouraged to report to the VMD. Reports are submitted on a special yellow reporting form (MLA252A). (Details on how to obtain these forms and where to send them are included at the end of this leaflet.) Pharmaceutical companies, manufacturers and retailers are also legally required to keep a record of any information they receive about suspected adverse reactions to their products and to pass these details to the VMD.

What happens to reports when they are received?

Every report to the VMD is acknowledged in writing within two working days of receipt and its contents are entered on a computerised database. All information in the report, and any information received subsequently, is treated in confidence. Each report is carefully examined to assess:

- The severity of the reaction.
- Whether there have been any previous reports to the same or similar products.
- Whether any further information is required.
- What follow up action is required.

There is a legal obligation for the VMD to send a copy of the report form to the company whose product is suspected but the person reporting the side effect has the option to ask for their name and address not to be disclosed.

Sometimes a questionnaire requesting further information will be sent to the person reporting the side effect. Where it is a person with a suspected side effect (rather than an animal) they may also be asked for authority for their relevant medical notes to be provided. All medical reports are treated confidentially. Further information may also be sought from the Health and Safety Executive (HSE).