

- to evaluate all harmful, unexpected side effects in humans exposed to veterinary medicines and
- 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 inserts, 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.

How can I report a harmful, unexpected side effect?

If you consider that you or your animal(s) have reacted badly to a veterinary medicine and you need veterinary/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 scheme. If possible take the medicine container (or label for a large pack) or packaging/insert leaflet with you.

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

What can I report to the scheme?

It is important that ALL harmful, unexpected side effects to veterinary medicines are reported to the scheme 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,
Addlestone
Surrey KT15 3BR
Telephone: 01932 338427
Fax: 01932 336618
Web: www.vmd.gov.uk**



**ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES**



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SUSPECTED ADVERSE REACTION SURVEILLANCE SCHEME



INVESTOR IN PEOPLE

What is the Suspected Adverse Reaction Surveillance scheme?

The Suspected Adverse Reaction Surveillance Scheme is a voluntary scheme for monitoring reports of suspected adverse reactions to **veterinary medicines** in both animals and humans throughout the UK. It is run by the Veterinary Medicines Directorate (VMD), an Executive Agency of the Department for Environment, Food and Rural Affairs (DEFRA).

What is a Suspected Adverse Reaction?

A suspected adverse reaction is a harmful and unintended reaction which may be due to exposure to a veterinary medicine administered to an animal at its normal dose. (In other words any harmful, unexpected side effect to a veterinary medicine.) The scheme monitors reactions both in animals and people who are exposed to the medicine. Adverse reactions in overdose situations are also recorded.

Does the scheme record anything else?

Yes. The scheme also records reports of instances where a 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 can occur when animals are being treated with veterinary medicines such as vaccines, antibiotics, anaesthetics, tick and flea control products or sheep dips. It can also occur in people who are exposed to veterinary medicines (eg self-injections, handling recently treated animals).

Which animals are covered by the scheme?

The scheme 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, unexpected side effect?

Harmful unexpected 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/treatment if you are affected;
- report the reaction to the scheme (see back panel for contact details).

Who can report a harmful, unexpected side effect and how?

Anyone can report to the scheme on 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 scheme. 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 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 scheme.

What happens to reports when they are received?

Every report to the scheme is acknowledged in writing within two working days 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; and
- what follow up action is required.

There is a legal obligation for the scheme 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 details/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).

How are reports involving people assessed?

After they have been assessed, all reports of unexpected 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: