How can I report an animal adverse event?

Veterinary biological products are regulated by United States Department of Agriculture, Center for Veterinary Biologics (USDA, CVB) under the Virus Serum Toxin Act. The CVB maintains a pharmacovigilance program. An adverse event report enters this program through several channels.

Adverse events may be reported to:

- Manufacturer. Many biologics manufacturers maintain veterinary services departments to handle such reports and may also offer diagnostic advice, treatment recommendations, and guidance on product use.
- Center for Veterinary Biologics. Once an adverse event has been reported to the manufacturer, CVB may be contacted at (800) 752-6255 to request reporting directions. A report of an adverse event may be filed by submitting the information via the Web, http://www.aphis.usda.gov/animalhealth/cvb_aer or by downloading or requesting a blank form and faxing the completed form to (515) 337-6120 or by mailing it back to the CVB.

Veterinary drugs, medicated feeds, and animal devices are regulated by the Food and Drug Administration, Center for Veterinary Medicine (FDA, CVM) under the Food Drug and Cosmetic Act. The CVM recommends that you first contact the manufacturer to report an adverse event. To contact CVM directly, call (888) FDA-VETS.

Topical insecticides. Most of the products used topically for the control of ectoparasites and insects on animals are regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide Fungicide and Rodenticide Act. The EPA recommends that you first contact the manufacturer to report an adverse event or call (800) 858-7378.

(01/08)

Pharmacovigilance
United States Department of Agriculture
Center for Veterinary Biologics
1920 Dayton Avenue
P.O. Box 844
Ames, IA 50010

U.S. Department of Agriculture
Center for Veterinary Biologics

Pharmacovigilance of Animal Biologics

Adverse Biologic Event Reporting System

A monitoring program for adverse events associated with the use of veterinary biological products

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What is a veterinary biological product?

A veterinary biological product is one which modulates the immune system for the prevention, treatment, or diagnosis of disease. Veterinary biological products are used to prevent disease include vaccines or toxoids which stimulate an animal to produce antibodies against specific organisms or substances. This is termed active immunization. Passive immunization may be obtained from antibody-containing products such as serum derivatives; they may be used to treat disease. Immunobiological reactions are increasingly used as the basis of test kits for the diagnosis of disease.

How is a veterinary biological product produced?

The immunologically active ingredients in a veterinary biological product may be either antigens or antibodies. Antigens are derived from killed or attenuated live disease organisms such as viruses and bacteria. Antibodies may be derived from the blood or milk of donor animals that are often immunized against specific antigens. Other components of veterinary biological products include the fluid suspension medium, preservatives or antibiotics, stabilizers, and adjuvants, which are substances which enhance the immune reaction. Licensed manufacturers of veterinary biologics are regularly inspected to verify that production is done in accordance with approved procedures. Products intended for use in animals must be tested for purity, safety, and potency before they may be marketed. As a further check on the manufacturer's quality control, the USDA regularly tests randomly selected lots of all products in its own laboratory.

What is the purpose of pharmacovigilance?

Pharmacovigilance of veterinary biologics has two main functions. One is to serve as an alert system for detecting the possibility that a product may not be performing as intended. An alert is triggered when information has been received which implicates a product in events which appear to be unusual in nature or frequency. The immediate response to an alert is an evaluation of the possibility the product is defective. The alert may be confirmed, rejected, or more information may be sought. Confirmation of an alert could trigger an intervention. Fortunately, this is a rare occurrence.

Pharmacovigilance also provides an essential source of descriptive baseline information about the behavior of a vaccine or other veterinary biologics when it is used under everyday field conditions. This type of information is a valuable reference in guiding our expectations and comparing situations which appear unusual. Temporal or geographical trends may become apparent.

What is an adverse event?

An adverse event is any undesirable occurrence after the use of a veterinary biological product, including illness or reaction, whether or not the event was caused by the product.

What adverse events may possibly occur after the use of veterinary biological products?

Some animals, like people, may be uncomfortable or lethargic the day they are vaccinated. More serious adverse events are a less common possibility. Immune (hypersensitivity) reactions are infrequent but possible after exposure to any veterinary biological product as well as many other substances. Acute anaphylaxis with immediate collapse is a dramatic reaction that may happen shortly after vaccination. It is important to observe an animal for at least an hour after vaccination, so that it may be treated if necessary. Other reactions that have been observed within a day of vaccination include loss of appetite, fever, facial swelling, hives, nasal or ocular discharge, respiratory distress, vomiting and diarrhea.

Events occurring a day to two weeks after vaccination include similar events as well as stiffness, local inflammation, and systemic illness which may or may not be based on an immune reaction.

If you have any concerns about the health of an animal after the use of a veterinary biological product, consult your veterinarian promptly. Your veterinarian is also an important source of guidance about the proper administration of veterinary biological products.

Not all properly vaccinated animals will be immune to disease under all circumstances. Many factors affect the response of a particular animal to vaccination and the chance that it will subsequently succumb to disease. Such factors include the animal's immune competency, its health at the time of vaccination, stress, environment, and the virulence of the pathogen.

Even under optimal conditions, antigens vary widely in the strength and duration of the disease protection they confer. A vaccine may be licensed for the prevention of disease or as an aid in the prevention of the disease depending on level of disease protection detected after vaccine administration in experimental studies.

How frequently do adverse events occur?

Good estimates of the rates of various types of adverse events after the use of veterinary biological products are not readily available. The information we have is based on voluntary spontaneous reports to manufacturers and the USDA. While it may be possible to calculate a reporting rate, the relationship between a reporting rate and an incidence rate is not clear. This relationship may vary by type and severity of event, species, manufacturer, and even from one month to the next. Reporting rates must always be interpreted cautiously. Under appropriate conditions, a reporting rate may sometimes be used to estimate minimum incidence, and for certain comparisons.

What happens when an adverse event is reported?

The mission of the USDA is to ensure that animal veterinary biologics are in compliance with the Virus Serum Toxin Act. Reports are assessed for the possibility of a product deficiency. When necessary, testing is performed or additional information sought. The USDA is, however, unable to make diagnoses or recommendations specific to individual cases. Some of the manufacturers do provide such services. Receipt of a report by the USDA does not necessarily imply that the product caused an adverse event, or even that a particular event actually occurred.

What should be done if a human is exposed to an animal veterinary biological product?

In the event of a serious human exposure to a veterinary biological product, such as inadvertently injecting oneself with a vaccine intended for animals, contact your physician or emergency room at once. Be prepared to inform your physician about the product you were exposed to. Your physician may wish to contact the manufacturer for additional information about the product. The Center for Veterinary Biologics may be able to facilitate the communication of important information, if necessary.