Pharmacovigilance FAQ

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The Veterinary Biologics Pharmacovigilance Program is for the ongoing surveillance of adverse events associated with animal vaccines and other immunobiologics, in cooperation with the veterinary profession and the veterinary immunobiologic industry.

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What is pharmacovigilance?

Pharmacovigilance of veterinary medicinal products (which includes immunobiologics) can be defined as the detection and investigation of the effects of the use of these products, mainly aimed at safety and efficacy in animals and safety in people exposed to the products.

What is an immunobiologic?

An immunobiologic product (also known as a 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 an immunobiologic produced?

The immunologically active ingredients in an immunobiologic 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 who are often immunized against specific antigens. Other components of immunobiologics include the fluid suspension medium, preservatives or antibiotics, stabilizers, and adjuvants, which are substances which enhance the immune reaction. Licensed manufacturers of animal immunobiologics 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 postmarketing surveillance?

Postmarketing surveillance of veterinary immunobiologics 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 as the cause of 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.

Postmarketing surveillance also provides an essential source of descriptive baseline information about the behavior of a vaccine or other immunobiologic 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 observation in animals, whether or not the cause of the event is known, that is unfavorable and unintended, and that occurs after any use (as indicated on the label or any off-label use) of a biological product, including events related to a suspected lack of expected efficacy. For products intended to diagnose disease, adverse events refer to a failure in product performance that hinders an expected discovery of the correct diagnosis.

What adverse events may possibly occur after the use of immunobiologics?

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 immunobiologic, 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, or 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 an immunobiologic, consult your veterinarian promptly.

Your veterinarian is also an important source of guidance about the proper administration of immunobiologics. 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.

How frequently do adverse events occur?

The frequency of adverse events occurring in animals may vary depending on various factors such as age, species, breed, weight, environmental conditions, and any pre-existing health conditions of the patient(s). The use of other immunobiological products, pharmaceutical products such as antibiotics, or parasiticides such as flea and tick control products at the same time may also effect the frequency rate. Although a baseline frequency rate may be established, variable conditions may modify the frequency rate. It is important to note that not all adverse events are reported and, not all adverse events reported are actually adverse reactions (cause and effect relationship resulting from the use of an immunobiological product).

What happens when an adverse event is reported?

The mission of the USDA is to ensure that animal immunobiologics 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 is 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.

How can I report an adverse event?

Veterinary immunobiologics are regulated by the USDA Center for Veterinary Biologics (CVB) under the Virus-Serum-Toxin Act. The CVB maintains a pharmacovigilance program. The manufacturers of veterinary biological products are

required to report all adverse events they receive to the CVB. Please contact the manufacturer to report adverse events. For information on how to report an adverse event, visit Adverse Event Reporting.

What should be done if a human is exposed to an animal immunobiologic?

In the event of a serious human exposure to a veterinary immunobiologic, 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 to which you were exposed. Your physician may wish to contact the manufacturer for additional information about the product. The CVB may be able to facilitate the communication of important information, if necessary.

Are manufacturers of veterinary immunobiological products required to report adverse event reports they receive to the USDA?

On June 18, 2018, the Federal regulation (230.41 KB) requiring manufacturers of veterinary immunobiological products to report adverse events to the CVB became effective; however, full implementation was delayed as explained in CVB Notice 18-09 (174.32 KB). Full implementation of the above referenced regulation regarding mandatory reporting of adverse events by all licensees and permittees will be begin on February 17, 2021, as stated in Veterinary Services Memorandum 800.125.

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