The label contains information about the disease that the vaccine is intended to prevent. If the disease produces many clinical syndromes, usually efficacy of the vaccine for only a single syndrome has been tested. Precisely which syndrome for which the vaccine was tested may not be stated on the label of older products, but the USDA now requires that specific disease syndromes be stated on the label of novel vaccines (ie, vaccines with an antigen or antigens not contained in any previously licensed products).

Vaccine labels contain 1 of 3 common wordings describing the level of protection afforded by vaccination. The wording "...prevents infection with (certain microorganism)" may be placed on the label if data demonstrates that the product is able to prevent all colonization or replication of the challenge micoorganisms in vaccinated-and-challenged animals. The wording "...indicated for the prevention of disease" normally applies to vaccines that have produced results consistent with the 80:80 efficacy guidelines. The wording "...indicated as an aid in the prevention of disease" is found on vaccines for which efficacy testing demonstrated a statistically significant difference between vaccinates and controls, but not of the level required for the stronger wording. There are several reasons why a reduced level of efficacy might be observed: the vaccine may be less effective, the challenge exposure may have been less severe, or the disease the vaccine attempts to attenuate may create only mild or subtle clinical signs. At any efficacy level, the manufacturer needn't demonstrate that protection induced by the vaccine is clinically apparent or relevant to an individual animal, or in the case of the latter 2 levels, that use of the vaccine will reduce the prevalence of disease in a population. There is also no requirement that the label state how the vaccine is best used in a preventive medicine program. For additional information on vaccine efficacy studies, see USDA-APHIS CVB Veterinary Services Memorandum No. 800.2000 (http://www.aphis.usda.gov/vs/cvb/lpd/memos/VSMemo800.200.PDF).

Label directions usually reflect the way the vaccine was used during the required safety and efficacy testing. For example, the label may contain the following directions: "Administer intramuscularly one ml dose of vaccine. Repeat in 2-3 weeks. Annual revaccination is recommended." There is no requirement to demonstrate that both doses are necessary or that 2 to 3 weeks is the optimal revaccination interval, nor is there a requirement to indicate how to proceed if the second dose is administered more than 3 weeks after the first.

Approximately 3 decades ago, the paucity of data regarding the duration of protection induced by canine vaccines led experts to recommend annual administration as an attempt to ensure maintenance of protection from disease throughout the life of an animal and to maintain long-term population immunity.[67,68] However, for the vast majority of animal vaccines currently available, the USDA does not require manufacturers to provide observational data on the label to support the recommendation for annual revaccination. The USDA does require manufacturers introducing vaccines containing novel antigens (ie, vaccines with an antigen or antigens not contained in any previously licensed products) to provide data demonstrating duration of immunity claims stated on the product label, but there is no requirement to determine the maximal or optimal revaccination interval.

The route of administration and dose volume indicated on the label should be carefully heeded, because they were probably the only ones tested for safety and efficacy during the licensing process. The practice of reducing the vaccine dose in an effort to reduce adverse post-vaccination events is unlikely to improve vaccine safety and may compromise effectiveness.

Vaccine labels often indicate the ages of animals to which the product may be administered. Age restrictions may exist for safety reasons, as a consequence of regulatory policy, or both. Unfortunately there is no way for the reader of the label to know under which set of rules the vaccine was approved, or why an age restriction is or is not indicated on the label. When in doubt, practitioners should consult with the vaccine manufacturer's technical assistance staff.

Other than warning of the possibility of anaphylactic reactions, vaccine labels have historically provided little safety information. The USDA is beginning to require that manufacturers list vaccine-mediated events (eg, fever, lethargy, or swelling at the injection site) observed during safety testing, but this requirement only applies to newly approved products or to older products for which the manufacturer is submitting changes to the USDA. Currently it is not possible for a reader to know why the label for one vaccine contains safety information not included on the label of a competitor's product. Consequently, labels of products that are nearly identical may list markedly different safety information; the converse is also true.[66] Vaccine users can attempt to clarify the confusion by contacting the manufacturer's technical assistance staff.

Adverse Events and Adverse Event Reporting

Despite the admirable safety record of animal vaccines, adverse events do occur. They may be local or systemic; mild, severe, or even fatal; or peracute, acute, subacute, or chronic; and may include vaccine-induced disease or failure to confer immunity. However, even when vaccination immediately precedes an adverse event, it may be difficult to determine with certainty whether the vaccine was responsible. There are many confounding factors that make it difficult to establish a cause-and-effect relationship between vaccination and subsequent illness or death (eg, simultaneous administration of more than 1 vaccine from the same or different manufacturers, concurrent administration of non-vaccine products, pre-existing disease, or prior exposure to the organism and incubation of disease at the time of vaccination).

Although reporting of adverse events associated with vaccination is not mandatory, it is helpful for all vaccine users to assist in development of databases of adverse