Evaluation of Potential Data Sources for Animal Drugs Used in Veterinary Medicine

Client: U.S. Department of Health and Human Services, Food and Drug Administration

Project Overview
The overall goals of this evaluation were to identify, describe, and evaluate the strengths and limitations of existing data sources that potentially could be included in the Food and Drug Administration’s (FDA) Sentinel Initiative. FDA’s Sentinel System was designed for near real-time monitoring of the postmarket performance of regulated medical products. This phase of the Sentinel work was designed to assess the feasibility of expanding this project to include animal drugs used in veterinary medicine. Thus, the goal of this research was to 1) identify the available data sources for animal drugs in several key animal care industries and 2) assess whether the data potentially could provide useful information on the safety of veterinary medical products using the approach envisioned for the Sentinel System.

The research consisted of 4 main phases:

1. Literature review and synthesis and development of an inventory of potential data partners that collect data related to exposure to approved veterinary medical products and animal health outcomes
2. Selection of data partners of interest to FDA for in-depth review
3. Development of descriptions/profiles of each of the selected data partners
4. Analysis of the data sources for their potential contributions to the Sentinel System

The final report characterized each data source (including quality and timeliness, scope, suitability for inclusion, and willingness of organizations to participate) and identified common issues across data sources. The report also identified potential next steps. Results of the study helped to provide FDA with a comprehensive analysis of the existing data sources, their strengths and limitations, and their potential role within any future active surveillance system to help FDA ensure the safety of approved veterinary medicine products.

Core Activities
Literature Reviews and Environmental Scans; Qualitative Research; Database Development; Policy Analysis and Assessment; Report Development and Presentation

Products
The final report is entitled “Evaluation of Potential Data Sources for Animal Drugs Used in Veterinary Medicine.” (September 2010)