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.

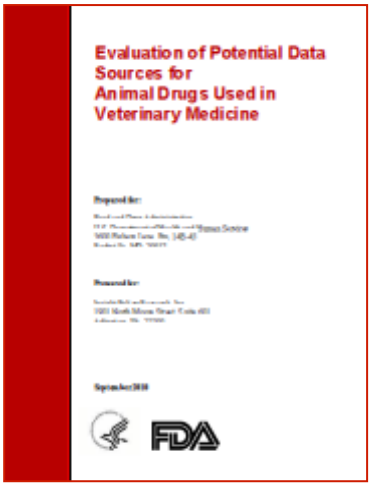
The research consisted of 4 main phases:

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

Cross-Comparison of Key Surveillance Database Characteristics

Database Characteristic	Angell Animal Medical Centers	Petplan USA	Veterinary Medical Database (VMDB)	Feedlot Health Management Services (FHMS)	Goldsboro Milling Company Inc.
DRUG INFORMATION					
At least one drug?	Yes	Not routinely	Yes	Yes	No
Brand/generic name	Yes	No	Yes	Yes	Yes-generic only
Dose	Yes	No	No	Yes	No
Timing	Yes	No	No	Yes	No
Route	Yes	No	No	Yes	No
ANIMAL INFORMATION					
Species	Yes	Yes	Yes	Yes	Yes
Age/age group/production stage	Yes	Yes	Yes	Yes	Yes
Reason drug given	Yes	Limited	Yes	Yes	Yes - group only
OUTCOME INFORMATION					
Morbidity	Yes	No	Yes	Yes	Yes - group only
Mortality	Yes	Yes	Yes	Yes	Yes - group only
Production parameters	No	No	No	Yes	Yes - group only
Time occurred	Yes	No	Yes	Yes	Yes - group only
POTENTIAL TO LINK					
Time between drug and outcome	24 hours	30 days minimum	1 month to 5 years	24 hours	Yes
Aggregate over time?	Yes	Yes	Yes	Yes	On paper at farms
Aggregate over animals?	Yes	Yes	Yes	Yes	On paper at farms

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)