

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

Overview

This evaluation identified, described, and evaluated the strengths and limitations of 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 aimed to assess the feasibility of expanding the project to include animal drugs used in veterinary medicine. The research (1) identified the available data sources for animal drugs in several animal care industries and (2) assessed whether the data could potentially provide useful information on the safety of veterinary medical products using the approach envisioned for the Sentinel System.

The research had four main phases:

- Literature review and synthesis and development of an inventory of potential data partners that collected data related to exposure to approved veterinary medical products and animal health outcomes
- Selection of data partners of interest to FDA for in-depth review
- Development of descriptions/profiles of each of the selected data partners
- 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 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.

Products

Final report, *Evaluation of Potential Data Sources for Animal Drugs Used in Veterinary Medicine* (September 2010)