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Editorial

Surveillance Approaches for Regulatory Science

Susie Y. Dai [a, b]

[a] *Office of the Texas State Chemist, Texas A&M AgriLife Research, Texas A&M University System, College Station, TX 77841, USA*

[b] *Texas A&M University, Department of Veterinary Pathobiology College Station, TX 77843, USA*

The essential function of a regulatory agency is to enforce laws enacted by the government and regulations established by the agency. For example, the US Food and Drug Administration (FDA) is charged with protecting public health by the regulation of food; pharmaceuticals, both over-the-counter and prescription; dietary supplements; medical devices; animal feeds; and veterinary medications. The effective regulation requires fit-for-purpose surveillance activities. Designing surveillance activities based on scientific theory and management through a science-based approach provides a repeatable and verifiable framework for iteratively gathering and analyzing data, and developing increasingly effective risk-mitigation techniques to support regulatory programs.

Surveillance scheme can be different for different category of regulated products. As regards food regulation, one aspect of surveillance involves monitoring and analyzing food hazards for the purpose of building effective risk management processes. For instance, measurement of aflatoxin contamination levels in animal feed and human food composes an important step for risk assessment and risk analysis. As regards drug regulation, post-marketing surveillance sets in place processes to monitor the safety of a drug or biologic after its release on the market. Collected information is analyzed and measures are taken if certain values related to the drug safety concerns are exceeded. In the United States, FDA Adverse Event Reporting System (FAERS) is designed for all FDA-approved drugs and therapeutic biological products and reports adverse events and medication errors that are submitted to FDA and is tracked using a computerized database system. For medical devices, FDA requires deaths, serious injuries and malfunctions to be reported by the manufactures. The system includes the Mandatory Medical Device Reporting System (MDR), voluntary reporting through the MedWatch system, hospital-based reporting through the Medical Safety Network (MedSun) and an international program in which the reports are exchanged with other global regulatory authorities.

This issue focuses on surveillance as it is applied to regulated products. Suzuki et al., in "A Comprehensive Analysis of Factors that Contribute to Conditional Approval and All-case Surveillance Designations that Subsequently Lead to Shortening of Review Times in Japan" describe using statistical methods to identify the potential factors that are likely to impact the "drug lag" issue in Japan. Drug lag

refers to the delay in introduction of a new pharmaceutical agent into a country, a concept first raised by William Wardell, a pharmacologist who noticed that often drugs available abroad are not accessible to American patients. Drug lags can impede the delivery of a beneficial drug to the patient population. With proper procedures implemented, the duration of drug lags necessary to ensure product safety before commercial release might be shortened. For drug administration, an optimized combination of facilitated new drug approval process and drug safety surveillance can increase drug accessibility while, ensuring drug safety review, as demonstrated by the Japanese case in this issue.

Keys et al., in "*Enterobacteriaceae* Complicate the Recovery of *Listeria monocytogenes* from Food Product Enrichments using Buffered Listeria Enrichment Broth," discuss the need to improve the selective enrichment procedure in the FDA Bacteriological Analytical Manual (BAM) method for sensitive detection and efficient recovery of *Listeria monocytogenes*. Improvements over the current food surveillance microbiological method will help better identify the pathogen risks in food. Dai et al., in "Heavy Metal Contamination of Animal Feed in Texas," report the application of a comprehensive analysis of heavy metals in feed ingredients and finished feed to facilitate risk assessment and risk management decisions. Heavy metal contamination and other chemical hazard surveillance are essential components in food safety surveillance schemes. Monitoring of contamination levels will aid in the understanding and characterization of food risks and facilitate comprehensive risk assessments.

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