

From fragmented reporting to real-time foresight: What the FDA's AEMS means for pharmacovigilance

A KEY QUESTION



What does the FDA's AEMS mean for Pharmacovigilance?

KEYWORDS

AEMS, Pharmacovigilance, Real-Time Data, Adverse Events, Signal Detection, Centralized System, Data Transparency, Cross-Product Surveillance, Organizational Readiness, FDA



The launch of the U.S. Food and Drug Administration's (FDA) Adverse Event Monitoring System (AEMS)¹ marks what is likely to be one of the most significant structural shifts in pharmacovigilance in recent years. For decades, adverse event reporting across FDA-regulated products operated within a fragmented architecture, with multiple databases each aligned to specific product categories, evolving independently and often lacking interoperability. That model is now giving way to a unified, real-time system that fundamentally changes how safety data is generated, accessed and acted upon.

Introduced on March 11, 2026,² AEMS consolidates a historically complex reporting landscape into a single platform spanning drugs, biologics, vaccines, devices, foods and tobacco products. Previously, stakeholders relied on distinct systems such as FAERS for drugs and biologics, VAERS for vaccines and MAUDE for medical devices. Each database held its own logic, processes and reporting cadence, creating operational inefficiencies and limiting the ability to identify safety signals across product categories. AEMS replaces that model with a centralized approach designed to standardize reporting, improve data quality and enable more sophisticated surveillance.

At its core, AEMS is not simply a technology upgrade. It represents a shift in regulatory philosophy from periodic visibility into safety data toward continuous, near real-time insight. Historically, adverse event data was published in quarterly cycles. This cadence shaped how companies structured their signal detection processes, internal review timelines and governance frameworks. Under AEMS, that temporal buffer is removed. Data is expected to be made available in real time, dramatically shortening the interval between report submission and public visibility.

Implications for the pharmaceutical industry

This acceleration has profound implications for the pharmaceutical industry. Safety signals that may previously have taken months to detect can now emerge within days. While statutory timelines for individual case safety report (ICSR) submission remain unchanged, the external visibility of those reports is significantly compressed. For marketing authorization holders, this introduces a new operational reality in which internal monitoring, analysis and decision-making must keep pace with a continuously updating data environment.

Equally important is the shift from siloed to cross-product surveillance. In the legacy environment, identifying patterns across different product categories was inherently constrained by data fragmentation. A signal involving a combination product, or a company portfolio spanning drugs and devices, might not be readily apparent when viewed through separate systems. By unifying these datasets, AEMS opens the possibility of detecting broader safety patterns that cut across therapeutic modalities. This has particular relevance for increasingly complex treatment paradigms, where patients may be exposed to combinations of therapeutics, devices and adjunct technologies.

Democratization of safety information or misinterpretation risk?

For the FDA, the benefits are both operational and strategic. Maintaining multiple independent databases carried significant financial and administrative costs. The transition to AEMS is projected to generate substantial savings over a five-year period while simultaneously enhancing the agency's ability to monitor, analyze and act upon safety data. The platform also expands beyond traditional adverse event reporting, serving as a central repository for consumer complaints, regulatory misconduct reports and whistleblower submissions. This integrated approach positions AEMS not only as a pharmacovigilance tool but as a broader engine for regulatory intelligence.

The increased transparency enabled by AEMS will also extend to healthcare professionals and the general public. The introduction of a user-friendly, interactive public dashboard allows stakeholders to query adverse event data more easily than before. This democratization of safety information reflects a broader trend toward openness in healthcare data. However, it also reinforces the need for careful interpretation. As with legacy systems, AEMS is based on spontaneous reporting, meaning that the presence of an adverse event report does not establish causality. The data may contain duplicates, incomplete records and reporting biases and it cannot be used to calculate incidence or prevalence rates. Without appropriate knowledge, there is a risk that raw data could be misinterpreted.

Organizations need to accelerate review cadences

For industry stakeholders, the transition to AEMS is therefore as much about organizational readiness as it is about technical adaptation. Traditional quarterly review cycles are no longer sufficient in an environment where data is refreshed continuously. Pharmacovigilance organizations must define clear ownership of AEMS monitoring and establish more frequent review cadences that support timely signal detection and risk management. This includes rethinking how signals are triaged, escalated and assessed within internal governance structures.

At the same time, foundational processes must be updated to reflect the new system. Standard operating procedures, training materials and submission templates that reference legacy databases will need to be revised. Organizations must also confirm readiness for upcoming regulatory requirements, including the October 1, 2026 transition to E2B(R3) standards.³ This involves validating submission pathways, ensuring coding consistency and strengthening duplicate management practices, particularly in light of the complexities introduced by data migration from legacy systems.



The role of intelligent technologies will also become more prominent. The FDA has signaled that artificial intelligence will play a role in scanning AEMS data for safety signals, enabling faster detection of patterns and clusters. As regulatory capabilities evolve, industry must respond in kind. Organizations will need to enhance their analytical capabilities and confirm that their internal systems can operate at a comparable pace and level of sophistication. This is not simply a question of technology deployment, but of embedding data-driven decision-making into the core of pharmacovigilance operations.

The demand for experience pharmacovigilance partners

In this context, the importance of an experienced pharmacovigilance partner becomes increasingly clear. Successfully navigating the transition to AEMS requires a combination of regulatory intelligence, operational discipline and scientific knowledge. Fortrea has been actively monitoring the FDA's progress on AEMS and assessing the implications for processes and systems. This preparation enables the organization to support clients in adapting to the new environment while maintaining compliance and inspection readiness.

Effective pharmacovigilance in the AEMS era will depend on establishing clear ownership, standardized processes and a quality-driven approach to execution.

It will also require the ability to scale operations without compromising scientific rigor. Improving data quality upstream, defining governance frameworks before signals emerge and building a responsive operating rhythm are all critical components of success. Monitoring how data is presented in the AEMS public dashboard and identifying any issues arising from historical data migration will be equally important.

Ultimately, AEMS replaces a safety reporting model that was fragmented, delayed and difficult to navigate with one that is centralized, dynamic and transparent. The shift to real-time data availability transforms adverse event reporting from a retrospective exercise into a continuous process of surveillance and insight generation. For the pharmaceutical industry, this represents both a challenge and an opportunity. Organizations that can adapt their processes, technologies and governance frameworks to this new reality will be better positioned to detect risks earlier, respond more effectively and reinforce trust in the safety of their products.

As pharmacovigilance continues to evolve, AEMS may well prove to be a defining milestone—one that moves the industry from reactive reporting toward proactive, data-driven foresight.

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