SFDA Joins MedDRA Management Committee: The 6th Global Regulatory Body

RIYADH, SAUDI ARABIA, June 4, 2025 /EINPresswire.com/ -- In a move that highlights Saudi Arabia's growing prominence in global pharmaceutical governance, the Saudi Food and Drug Authority (SFDA) has been officially elected to the Management Committee of the Medical Dictionary for Regulatory Activities (MedDRA)—becoming the sixth regulatory authority worldwide to join this Committee.

This election marks a pivotal milestone for both the Kingdom of Saudi Arabia and the international scientific community, reflecting global confidence in the SFDA's regulatory excellence and the Kingdom's strategic role in advancing international harmonization in drug safety and medical product oversight.

MedDRA—developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)—is a globally recognized standard for coding and analyzing safety data across the lifecycle of pharmaceutical and biopharmaceutical products. It plays a central role in regulatory communication, post-market surveillance, clinical trial reporting, and signal detection.

SFDA's election to the MedDRA Steering committee was confirmed during the ICH Management Committee meeting held in Madrid, Spain, from May 11–12, 2025. With this appointment, SFDA joins a group of regulators, including the European Commission, U.S. FDA, UK MHRA, Health Canada, Japan's MHLW and PMDA—alongside the World Health Organization (WHO), which participates as an observer.

This strategic appointment reaffirms SFDA's active leadership within ICH working groups, particularly in the areas of medical terminology and pharmacovigilance. Among its most impactful contributions is the linguistic and technical leadership demonstrated in the translation and validation of over 20,000 MedDRA terms into Arabic—a landmark initiative completed between May and October 2022. This achievement significantly facilitates the implementation of MedDRA across Arabic-speaking regions and enhances inclusive pharmacovigilance throughout the MENA region.

For CEOs, scientific leaders, and policymakers, this development signals new opportunities to align regulatory frameworks, accelerate clinical development across the region, and enhance data interoperability. SFDA's presence on the MedDRA Steering Committee is not merely symbolic—it serves as a strategic platform for integrating global safety data, advancing regulatory innovation, and sharing best practices.

As Saudi Arabia continues to lead in biopharma localization, digital health, and AI-driven pharmacovigilance, SFDA's role in shaping the evolution of MedDRA is set to reinforce the Kingdom's position at the forefront of global health regulation.

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