



## Beyond Regulation:

# Technological Advancements in Pharmaceutical Oversight



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In the evolving realm of pharmaceutical oversight, the Saudi Food and Drug Authority's (SFDA) Pharmacovigilance Executive Directorate is key to patient safety. Comprising four specialised departments, its foundation lies in the National Pharmacovigilance Centre, which emphasises data capture, signal detection, product quality and inspection. The second department addresses risk management and drug safety, ensuring a comprehensive approach to pharmaceutical oversight, while the third department focuses on medical errors, highlighting the importance of error prevention and mitigation in medical products. The fourth department is dedicated to cosmetics, encompassing two sections – cosmetics adverse reports and safety report analyses. Each entity plays a crucial role in upholding the quality and safety of medical products in the Kingdom, collectively contributing to the overarching goal of ensuring patient safety and improving regional standards in the Saudi health care system.

**Education and Training**

The SFDA actively engages in education and training programmes, cultivating a culture of awareness and expertise in pharmacovigilance. Collaborating with international regulatory agencies, the SFDA focuses on risk communication, disseminating knowledge to health care providers and the public. In addition, the SFDA plays a pivotal role in shaping the future of health care by integrating pharmacovigilance courses into university curricula.

Embracing the digital era, the SFDA introduced a user-friendly mobile app that empowers customers to identify risks, report issues, access information on registered medications and prices, and receive an overview of medication-related services. In its commitment to public health, the SFDA employs a multifaceted approach to minimise risks. From the creation of informative brochures, medication guides and patient consent forms, to leveraging modern communication tools like video content, the SFDA works to distribute crucial information efficiently and effectively.

**Reporting and Monitoring**

The SFDA's dedication to vigilance is evident in its robust reporting system, which is designed to empower health care practitioners and the public to promptly report potential safety concerns. Collaborative efforts with national and international pharmacovigilance agencies further enhance the SFDA's ability to identify and address emerging safety issues in a timely manner.

In an era in which data privacy is paramount, the SFDA employs a meticulous approach. Patient information is anonymised, and the responsibility for maintaining anonymity lies with health care providers, who are responsible for maintaining confidentiality and compliance with stringent privacy standards.

**Capacity Building**

The SFDA demonstrates its commitment to capacity building through stakeholder workshops, during which pharmaceutical and health care practitioners convene to exchange insights and knowledge. An upcoming education platform is set to release short courses tailored for health care practitioners, specifically focusing on high-risk and specialised measures, thereby enhancing overall expertise in the field.

As the SFDA aims to enhance client engagement, gather feedback for improved decision-making and embrace digitisation in its communication processes, the authority addresses challenges with strategic initiatives. An education platform housed under the SFDA academy is set to release short courses tailored for health care practitioners by the end of 2023.

### **Conclusion and Outlook**

The SFDA envisions storytelling videos as a powerful tool to effectively communicate the safety and impact of medications. Plans include post-authorisation studies at both national and international levels, with market authorisation holders actively participating in poster presentations and research projects.

The SFDA's Pharmacovigilance Executive Directorate is not just a regulatory body, but a dynamic force that is actively adapting to the evolving health care landscape. As the SFDA forges ahead, it remains steadfast in its commitment to realising Vision 2030's health care aspirations, safeguarding the Kingdom's well-being.

