الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

(SVN) Saudi Vigilance Newsletter

A publication by the Saudi Food & Drug Authority (SFDA) dedicated to pharmacovigilance awareness, drug safety updates, and regulatory excellence in the Kingdom of Saudi Arabia

In This Issue

Welcome to the inaugural issue of the Saudi Vigilance Newsletter — your gateway to understanding pharmacovigilance activities at SFDA

April – June 2026

Preface

This inaugural issue of SVN aims to familiarize healthcare professionals (HCPs) and other stakeholders with the pharmacovigilance activities at the SFDA.

Each section provides an overview of a specific activity and the responsible department, their mandates, key functions, and how they contribute to safeguarding public health in the Kingdom.

We hope this newsletter serves as a valuable reference and strengthens the collaborative relationship between the SFDA and the healthcare community.

TABLE OF CONTENTS

01 PHARMACOVIGILANCE ACTIVITIES

National Pharmacovigilance Center (NPC)

The National Pharmacovigilance Center (NPC) at SFDA, monitors the safety of medicinal products after they reach the market by receiving and evaluating reports of adverse drug events (ADEs) related to pharmaceutical products registered in the Kingdom of Saudi Arabia. ADEs is defined as a response to a medicine that is noxious and unintended and that occurs at doses normally used in humans. These reports include adverse drug reactions (ADRs) submitted by HCPs, suspected unexpected serious adverse reactions (SUSARs) reported by clinical research organizations (CROs), and lack-of-efficacy cases (LECs) submitted by relevant stakeholders.

Upon receipt, each case is evaluated to distinguish expected from unexpected adverse events. Based on these evaluations, and in collaboration with relevant departments, the NPC develops recommendations to minimize and prevent the recurrence of such events during future use of medicines. NPC also monitors the pharmacovigilance systems of pharmaceutical companies to ensure compliance with the requirements of the guideline on Good Pharmacovigilance Practices (GVP).

- **International Standards and Compliance**
  NPC monitors pharmacovigilance systems of pharmaceutical companies to ensure compliance with the requirements outlined in the GVP. NPC has adopted principles and standards of the International Council for Harmonisation (ICH) pharmacovigilance guidelines, including E2B guideline for electronic transmission of ADRs, ICH E2A (Clinical Safety Data Management), and other applicable ICH guidelines.

- **Guidance on Adverse Drug Events Reporting for Healthcare Professionals**

02 PHARMACOVIGILANCE ACTIVITIES

Drug Safety & Risk Management

Medicinal products play a critical role in the prevention, treatment, and management of diseases; protecting patient from potential adverse effects is equally important. As innovative therapies, biologics, and advanced treatment modalities continue to enter an increasingly complex healthcare environment, they offer significant clinical benefits while introducing risks that require continuous monitoring throughout a product's lifecycle.

The Drug Safety and Risk Management Department at the SFDA is responsible for the continuous evaluation of the safety of medicinal products during the post-marketing phase. The Department reviews scientific assessments of the benefit–risk profiles of medicinal products and conducts proactive safety surveillance of products registered in the Kingdom, drawing on multiple data sources, including scientific literature, epidemiological studies, clinical trials, and post-marketing safety reports.

The Department also reviews and approves risk management plans (RMPs) and additional risk-minimization measures (aRMMs), and evaluates safety-related updates to product information. Through robust safety surveillance, transparent communication, and proactive risk-minimization strategies, the Department plays a vital role in improving patient outcomes, protecting public health, and promoting the safe and effective use of medicines in the Kingdom.

Key Resources

- Risk Minimization Measures: Latest information on medications that need extra safety precautions beyond standard labeling. View RMM → sfda.gov.sa/en/RMM
- Safety Alerts: SFDA's Safety Alert portal to inform healthcare professionals about potential medication risks. View Safety Alerts → sfda.gov.sa/en/SAFETY_ALERT
- Medicines Under Close Monitoring : medicines that require close monitoring due to potential safety signals of serious risks : View Medicines Under Close Monitoring→ https://www.sfda.gov.sa/en/drug-safety-initiatives

03 PHARMACOVIGILANCE ACTIVITIES

Quality of Pharmaceutical Products

The Pharmaceutical Product Quality Department at the SFDA oversees pharmaceutical quality to prevent any defects from compromising the safety and efficacy of marketed products. This oversight combines reactive and proactive activities designed to ensure continuous compliance with approved standards and to protect patients from substandard medicines.

To accomplish this, the Department implements post-marketing surveillance programs, evaluates quality-related reports, and assesses defects or deviations that may affect product quality and efficacy. It also reviews laboratory testing results, issues product recalls when necessary, and ensures compliance with applicable regulatory requirements.

The Department's responsibilities further include evaluating requests for testing exemptions in accordance with established regulatory criteria, and assessing technical data and scientific evidence regarding products exposed to non-compliant transportation or storage conditions — a process that involves reviewing stability studies and conducting scientific risk assessments to determine product quality before regulatory decisions are made. Applying a risk-based approach to prioritize its surveillance activities, the Department oversees the quality of marketed human, biological, herbal, and veterinary medicines and performs trend analyses on quality-related data. Through collaboration with national and international regulatory authorities, monitoring of rapid alerts and quality-related safety signals, and implementation of necessary regulatory actions, the Department contributes to protecting public health and ensuring the continued availability of safe, effective, and high-quality pharmaceutical products.

Key Activities

- Post-marketing surveillance programs for pharmaceutical products
- Evaluation of quality-related reports and defect assessments
- Laboratory testing review and product recall management
- Oversight of human, biological, herbal, and veterinary medicines

SFDA guideline for HCPs to report suspected quality defects in pharmaceutical products.

04 PHARMACOVIGILANCE ACTIVITIES

Medication Errors

Medication errors are preventable events that may lead to inappropriate medication use or patient harm while a medicine is under the control of a healthcare professional, patient, or consumer. They may occur at any stage of the medication-use process, including prescribing, dispensing, administration, monitoring, storage, labeling, packaging, and product naming.

The Medication Errors Department plays an important role in preventing medication errors by focusing mainly on product-related medication errors—which may occur due to look-alike or sound-alike product names, similar product packaging, design similarity between two or more products from the same company, or unclear labels—and promoting the safe use of medicines in the Kingdom.

During the pre-registration phase, the Department evaluates medicinal product names, packaging, labeling, and critical safety information to reduce the risk of confusion, including look-alike/sound-alike names, unclear strength expressions, and packaging or labeling elements that may contribute to errors.

In the post-registration phase, the Department monitors and evaluates medication error reports submitted through SFDA reporting channels. Each report is reviewed to identify possible causes, contributing factors, and appropriate corrective or preventive actions, which may include updates to labeling or packaging, communication with marketing authorization holders, safety recommendations, or other regulatory measures to prevent recurrence.

✓ Key Initiatives

Key initiatives include improvements to packaging and labeling requirements, clearer expression of medicine strengths using metric units, warning statements for high-risk products such as neuromuscular blocking agents, and practical tools to support safe medication use.

✓ Guidance for Medication Error Reporting

05 PHARMACOVIGILANCE ACTIVITIES

Cosmetic Products Safety

Cosmetic products are substances or mixtures intended for external application to the human body — for cleaning, perfuming, protecting, maintaining good condition, or altering appearance — without a medicinal or therapeutic purpose. They include a wide range of products such as skin care products, fragrances, makeup, hair care products, and oral hygiene products. Although generally safe when used as intended, they may cause undesirable effects in some individuals, such as skin irritation, allergic reactions, redness, itching, or effects involving the eyes or oral cavity. The Cosmetic Products Safety Department plays a key role in safeguarding public health by monitoring and evaluating the safety of cosmetic products marketed in the Kingdom. The Department reviews safety reports, assesses risks associated with ingredients, claims, labeling, and conditions of use, and provides regulatory recommendations in accordance with applicable regulations and technical requirements.

The Department also supports post-market surveillance activities, reviews international safety alerts and regulatory updates, analyzes emerging safety concerns, and contributes to the development of regulations and guidance documents. In addition, it promotes awareness among consumers, healthcare professionals, and industry stakeholders regarding the safe use of cosmetic products.

Key Resources

- Cosmetics Warnings List: Alerts the public about cosmetic products that pose health risks or fail to meet safety standards. View Cosmetics Warnings → sfda.gov.sa
- Guidelines on Reporting Undesirable Effects, Recalls & Manufacturing Errors of Cosmetics

06 PHARMACOVIGILANCE ACTIVITIES

Drug Risk Communication

Drug risk communication is an essential component of pharmacovigilance and public health protection. It aims to provide accurate, timely, and evidence-based safety information about medicines to healthcare professionals, patients, consumers, and relevant stakeholders. Effective communication supports informed decision-making, promotes safe medicine use, and helps reduce preventable harm.

The Drug Risk Communication Department communicates important safety information related to medicinal products marketed in the Kingdom of Saudi Arabia. The Department develops and disseminates drug safety communications, educational materials, safety alerts, awareness messages, newsletters, and other risk communication outputs through SFDA's digital platforms and stakeholder engagement activities.

The Department works closely with internal and external stakeholders to ensure that safety messages are scientifically accurate, clear, targeted, and aligned with regulatory decisions and risk minimization measures. These communications may address new safety concerns, product information updates, medication safety recommendations, adverse drug reactions, safe-use instructions, or emerging public health issues. The Department also supports awareness and capacity-building initiatives for healthcare professionals, patients, and the public, while strengthening partnerships with healthcare institutions, professional societies, academic organizations, and national stakeholders. Through proactive communication, stakeholder engagement, and evidence-based messaging, the Department supports SFDA's mission to promote medication safety, strengthen public confidence, and protect public health in the Kingdom.

Communication Channels

- Drug Safety Labeling Updates: Inform healthcare professionals about recent changes in the safety information of medicinal products registered in Saudi Arabia. View Labeling Updates → sfda.gov.sa

SUCCESS STORY

Robotic Process Automation (RPA) in Signal Detection

In an effort to enhance the efficiency and accuracy of pharmacovigilance operations, the SFDA has implemented Robotic Process Automation (RPA) technology in its signal detection processes. This innovative approach leverages artificial intelligence and machine learning algorithms to automate the identification of potential safety signals from large volumes of adverse event data.

The RPA system continuously monitors incoming reports, applies statistical disproportionality analysis, and flags potential signals for expert review. This automation has significantly reduced the time required for routine signal screening while improving the consistency and reproducibility of the process.

Key Achievements

- Reduced signal detection processing time by over 60%
- Improved consistency and reproducibility of signal screening
- Enhanced capacity to process growing volumes of safety data
- Enabled pharmacovigilance experts to focus on complex clinical assessments
- Aligned with international best practices in automated pharmacovigilance

60%+
Reduction in signal detection processing time

100%
Improved consistency & reproducibility of screening

↑ Greater capacity to process growing data volumes

Aligned with international best practices in automated PV

Get Involved

Your participation strengthens pharmacovigilance in Saudi Arabia

Why Reporting Matters

Identifies new or rare adverse drug reactions not detected in clinical trials

Helps protect patients by enabling timely regulatory action

Contributes to the national and global drug safety knowledge base

Supports evidence-based updates to product safety information

SFDA Pharmacovigilance Resources

SFDA Official Website— Saudi Food and Drug Authority website

Saudi Vigilance Reporting Portal — Unified Electronic Reporting System to submit adverse events or quality defects

Risk Minimization Measures — Repository for approved educational materials and Risk Minimization Measures (RMM)

Safety Alerts — Latest safety alerts, and warnings regarding medical products.

Drugs Circulars and Withdrawal — Published recall actions in a searchable database

SFDA Guidelines Portal — Regulatory Guidelines

Drug Safety Labeling Updates — Latest changes in product safety information

Cosmetics Warnings List — Products Alerts

Topics of Interest — Awareness portal

Contact & Feedback

For inquiries and feedback, please contact us

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